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COMMONWEALTH OF KENTUCKY
PIKE CIRCUIT COURT - DIV. II
CIVIL ACTION NO, 07-CI-01303

COMMONWEALTH OF KENTUCKY, ex rel.
JACK CONWAY, ATTORNEY GENERAL PLAINTIFF

VS. VIDEO DEPOSITION FOR THE PLAINTIFF

PURDUE PHARMA L.P., et al. DEFENDANTS

* * *

DEPONENT: RICHARD SACKLER, M.D.

DATE: AUGUST 28, 2015

* * *

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VIDEOGRAPHER:

GEORGE PARKER

* * *

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The video deposition of RICHARD SACKLER, M.D., taken in the offices of Dolt, Thompson, Shepherd & Kinney, 13800 Lake Point Circle, Louisville, Kentucky, on Friday, the 28th day of August, 2015, at approximately 9:11 a.m.; said deposition being taken pursuant to Notice for use in accordance with the Kentucky Rules of Civil Procedure.

* * *

VIDEOGRAPHER: We are on the record at 9:12 a.m., August 28th, 2015 in the matter of Commonwealth of Kentucky, Pike Circuit Court, Division 2, Civil Action No. 07-CI-01303, The Commonwealth of Kentucky versus Purdue Pharma. This is the deposition of Dr. Richard S. Sackler.

If I could have the attorneys state their name into the record.

MR. THOMPSON: Do you want to just go ahead and read the list of the names?

VIDEOGRAPHER: Just read the list?

MR. THOMPSON: I'll tell you what, let's just go ahead, let's just say our names.

MR. SAYERS: Jason Sayers on behalf of Abbott.

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MR. DANFORD: Dan Danford on behalf of the Purdue defendants.

MR. STRAUBER: Donald Strauber on behalf of the various Purdue defendants.

MR. SILBERT: Oh, sorry. Richard Silbert in-house at Purdue.

MR. HENNEBERRY: Jay Henneberry on behalf of the Purdue defendants.

MR. THOMPSON: Tyler Thompson on behalf of the State of Kentucky.

MR. ELLIS: Anthony Ellis on behalf of the State of Kentucky.

MR. DENHAM: And Mitchell Denham from the Attorney General's Office on behalf of Kentucky.

RICHARD SACKLER, M.D., after first being duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. THOMPSON:

Q. Would you state your name, please.

A. Richard Sackler.

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Q. And you are here today to give testimony in a case pending against Purdue, various entities by the State of Kentucky.

Are you aware of that?

A. That's my understanding.

Q. And you've given --

MR. STRAUBER: Mr. Thompson, before you get started, I'd just like to note that I expect we will be designating portions of this transcript as confidential pursuant to the order.

MR. THOMPSON: Is that correct, Mitchell?

MR. DENHAM: Yeah, they can designate portions confidential, and then there's provisions about challenging them.

MR. THOMPSON: We won't disseminate until you-all designate and we respond.

MR. DANFORD: There's a 30-day period in the rule. We'll get you a copy of the agreed protective order.

MR. THOMPSON: And just so you know -- I know you're not from Kentucky; is that correct?

MR. STRAUBER: That's correct.

MR. THOMPSON: All objections, other than to the form of the question, are preserved in

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Kentucky on video.

MR. STRAUBER: Thank you.

BY MR. THOMPSON:

Q. What is your current role at Purdue?

MR. STRAUBER: Excuse me. I -- there are a number of defendants that bear some portion of the Purdue name, and the distinction can be significant. So I'd ask when you phrase your questions, specify which Purdue entity you are talking about.

Q. Well, let's -- let's talk about the number of Purdue entities there are.

How many Purdue entities are there?

A. I don't know.

Q. I've seen upwards of 69 different corporations, perhaps, that the Sackler family owns. Is that correct?

A. If you've counted them. I can't differ with you. I don't know the answer.

Q. There are a number of Purdue entities. The Purdue Frederick Company, Inc., does it still exist?

A. I don't know.

Q. Tell me what companies that you currently have a role with that involve Purdue.

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A. Purdue Pharma.
Q. Do you sit on the board of any other Purdue companies?
A. Not to my knowledge.
Q. What about Mundipharma?
A. I sit on the board of a consulting firm which consults to Mundipharma.
Q. Does the Sackler family own Mundipharma?
A. Yes.
Q. What about -- what is Mundipharma?
A. Mundipharma is -- is a name that is attached to many different companies, such as -- just similar to Purdue.
Q. Is that company over in Germany?
A. There is a Mundipharma company in Germany.
Q. What about Roxane? Does Purdue own Roxane?
A. No.
Q. Did they own Roxane in the past?
A. Never.
Q. All right. Do you know how many current companies are owned by the Sackler family?
A. No.

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Q. All right. In discussing OxyContin, how many companies were involved in the production, manufacturing or distribution of OxyContin?
A. Could you specify the geography?
Q. In the world.
A. Many. I've never counted them.
Q. Does Purdue do licensing agreements with other companies to sell OxyContin?
A. It does.
Q. Do they own parts of those companies?
A. No.
Q. How many companies does Purdue own that distributes or dispenses OxyContin?
A. Many.
Q. Can you tell me the names of them?
A. A few of them, but not all of them.
Q. Are you still the director of Purdue Pharma, Inc.?
A. I'm not sure.
Q. Are you still a general partner of Purdue Pharma, L.P.?
A. I am not. It is owned by two trusts.
Q. On July 30th of 2014, were you a director of Purdue Pharma, Inc.?
A. Not that I'm aware.

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Q. This is an affidavit filed in the Southern District of West Virginia.
And does that appear to be your name (indicating)?
A. That does.
Q. And it's dated July 30th, 2014. It says "Declaration of Dr. Richard S. Sackler. I am a director of Purdue Pharma, Inc., the general partner of Purdue Pharma, L.P. I've held this position since 1990."
A. If that's what it says, then that's what it says.
Q. How involved are you in the production and marketing and promotion and the training and management of Purdue sales representatives for OxyContin?
MR. STRAUBER: I object to the form of the question.
A. Should I answer?
Q. Go ahead.
MR. STRAUBER: You can answer.
A. It depends on the time.
Q. Okay. And when you say "it depends on the time," why do you say that?
A. Because I was involved in the areas at

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a supervisory level, not as an active level, for a period of time that began with the launching of OxyContin and ended in early 2003.
Q. When you were involved on the supervisory level but not the active level, how much of your day-to-day activity was devoted to OxyContin?
A. It varied enormously.
Q. In this declaration it says, "During the time period set forth in the amended complaint, 1996 to 2009, I was not directly involved with the day-to-day marketing or promoting of OxyContin, the training or management of Purdue sales representatives, or the scientific research into the conversion ratio from MS Contin to OxyContin. Those responsibilities principally fell to Purdue senior management in research and development, regulatory affairs, sales training and marketing, among others."
Is that accurate?
A. Yes.
Q. I want to show you an e-mail, Dr. Sackler, dated Monday, May 31st, 1999.
Do you know who Cornelia -- Dr. Cornelia Hentzsch is?
A. I do.
Q. And who is that?

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A. She was general manager of Mundipharma Australia.

Q. And to give this a little bit of context, you-all had a drug called MS Contin, morphine sulfate, that was an immediate-release narcotic opioid -- or narcotic; is that correct?

A. It was controlled release.

Q. Controlled release. I'm sorry.

And that was used primarily for cancer patients or malignant pain patients; is that correct?

A. The majority of use, yes; but not -- I don't think "primarily" conveys an accurate picture.

Q. Majority of use was for?

A. Over 50 percent.

Q. And it was sort of felt by Purdue Pharma that morphine had a stigma attached to it that kept doctors from prescribing it across the board; is that accurate?

A. Yes.

Q. And you-all had a --

A. May I amend that?

Q. Yes.

A. It didn't prevent doctors from prescribing it across the board. It was an inhibition to the use of a product in every application.

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Q. Have you ever gone back and studied the history of addiction and how it has played out in the 19th and 20th centuries?

A. I'm not a student of that literature.

Q. All right. What was your understanding of why doctors did not want to prescribe morphine for anything or had a stigma about prescribing it for anything other than cancer and malignant pain?

A. As I said before, the stigma prevented many physicians from prescribing it for any pain.

Q. Why do you think that stigma existed?

A. I'm not a student of the issue, but I believe the stigma existed because of a popular understanding shared by both professionals and by laymen that morphine was an end-of-life drug, if it was to be used at all.

Q. Were there concerns about addiction and dependence with respect to morphine?

A. Some people had those concerns.

Q. So going back to building our context here. You-all had a drug called MS Contin that you had the exclusive right to sell; is that correct?

A. That's correct.

Q. Do you know when that exclusivity was set to expire?

A. I'm -- I'm not certain that I know the date, no.

Q. Do you recall that one of the concerns that Purdue's senior management had -- and I'm using "Purdue" in relation to Purdue companies that are involved with OxyContin. And rather than just sit here and name them all out, can we agree that when I say "Purdue," I'm referring to Purdue companies of all the OxyContin?

MR. STRAUBER: Mr. Thompson, I have to object to that because I said at the outset there are different Purdue entities that are defendants in the case, and the distinction between them may at times be significant. And so if you lump them all together under "Purdue," we're going to get a record that will not be easily decipherable at the end.

Q. Well, let's -- let's talk about it then.

Which Purdue companies were involved in the sale and distribution of OxyContin?

A. Both Purdue Frederick and Purdue Pharma were involved in the early years of selling the product.

Q. Okay. Were there any other Purdue companies involved in the selling of the product?

A. Not in the U.S.

Q. Who had the exclusive right to sell MS Contin?

A. At first it was Purdue Frederick.

Q. And --

A. I don't know at what point Purdue Pharma acquired rights to sell it or if it did at all.

Q. What is the distinction between Purdue Frederick and Purdue Pharma?

A. Purdue Frederick was the original company that my father and uncle acquired in 1952. It was a shell company and it was the first pharmaceutical company that they owned.

Purdue Pharma was established in the early 1990s to take on new products and to also take on the risk of -- well, take on the risk of new products and also a few established products, but not all.

Q. Were there any actions taken with respect to Purdue -- or with respect to OxyContin that would not fall under the Purdue Pharma umbrella?

A. I'm sorry, could you repeat the question?

Q. Yeah. Are you -- are you maintaining

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that there are any actions done with respect to OxyContin, its -- its creation, production, marketing, sales, that do not fall under the Purdue Pharma umbrella?

A. Its creation was done in Purdue Frederick --

Q. Okay.

A. -- until the early '90s when that responsibility was transferred to Purdue Pharma.

Q. And then Purdue Frederick continued to exist, though, correct?

A. It did.

Q. Okay. And was Purdue Frederick also a company involved with marketing, promoting, sales and production of OxyContin?

A. I'm trying to give you an accurate answer because this is confusing and complex.

There was a period of time in which once Purdue Pharma became involved that Purdue Frederick was involved, but Purdue Frederick was never involved nor Purdue Pharma in manufacturing the drug, which was when it was developed, was manufactured by a company named P.F. Laboratories.

Q. Okay. Other than the manufacture, did Purdue Frederick and Purdue Pharma both play a role in the production of it?

A. I can't recall in detail whether they both played a role or whether when Purdue Pharma took on the project it carried most of the weight or all of it.

Q. Is there any difference between the employees of Purdue Frederick and Purdue Pharma?

A. There were differences.

Q. Okay. Any difference in the board of directors?

A. That would test my memory, and I'm not sure.

Q. All right. Well, let me go back to -- let's talk about OxyContin. And I'm going to use the term "Purdue" for both Purdue Frederick and Purdue Pharma. If at some point you feel like there's a distinction to be made, you let me know. Okay? But at a time when --

MR. STRAUBER: Mr. Thompson, I object to your combining the two under the name "Purdue." If you're going to do it, then I'd like to have a standing objection to that combination.

MR. THOMPSON: What is your reason for the objection?

MR. STRAUBER: My reason is, as Dr. Sackler has explained briefly, they were two entities that did different things at different times, and if you lump the two together, inevitably there's going to be confusion in terms of the witness's answer.

Q. Okay. Let's do this. I'm going to refer to Purdue as Purdue Pharma, L.P. and also Purdue Frederick, L.P. If at some point you feel like it's only Purdue Frederick or only Purdue Pharma, you let me know. Okay?

A. It's kind of a burden, but with the help of my attorney...

Q. Sure.

A. Because there may be issues. It's going to be -- it tests my memory to separate the two. So I'm sorry for the confusion, but it is important.

Q. For instance -- let me ask you this. Sales reps. Were sales reps employed by Purdue Frederick or Purdue Pharma?

A. For a period of time they were -- each sales rep was employed by one, but not necessarily the other.

Q. Do you know which sales reps were employed by Purdue Frederick versus Purdue Pharma?

A. I don't know.

Q. Do you know if they received different training?

A. I believe the training was the same.

Q. Well, I'll tell you what, I'm going to refer to when I say "Purdue" as Purdue Frederick. If you feel like it's Purdue Pharma, you let me know. Okay?

A. Okay.

Q. All right. So back in 19 -- early '90s when you were developing MS Contin, this exclusive license that you had to sell MS Contin was going to expire and there was going to be competition from generic companies, correct?

A. Well, the product MS Contin was developed in the late '70s and early '80s. And -- so are you discussing development or are you discussing a later time?

Q. The later time when its license is about to expire.

A. Eventually we knew that there would be competition for MS Contin.

Q. And one of the things in developing Oxycodone Controlled-Release, one of the -- one of the concerns was how to position it in the market and whether you were going to position it an obsolete

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MS Contin or try to position it alongside MS Contin. Do you recall that issue?

MR. STRAUBER: I object to the form of the question. Could you repeat it? I'm not sure I understood the question.

MR. THOMPSON: Yes.

Q. One of the concerns when you were developing Oxycodone -- I'm sorry -- OxyContin Controlled-Release was how you were going to position it for market share and whether you were going to position it and make MS Contin obsolete and take that market share that MS Contin had, or whether you were going to position it alongside MS Contin and sell them both together.

Do you recall that concern?

A. I recall discussions, but that wasn't the principal driver. The principal -- the principal goal was to produce the best product we could, and we believed when we started it and subsequently...

Should I stop?

Q. No, no.

A. We believed it was and is a better product than MS Contin.

Q. Here's a memo dated -- to Richard S. Sackler from Robert Kaiko.

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Do you know Dr. Kaiko?

A. I do.

Q. He's a Ph.D.?

A. He is.

Q. What was his role?

A. He was the person who undertook or ran the project and was involved -- the project of developing OxyContin -- and was -- as a clinical pharmacologist was deeply involved in selecting formulations that would be most likely to achieve the desired effect.

Q. And under here it says, "Rationale for Another Controlled-Release Opioid Analgesic."

This is Bates number -- it's actually got two Bates stamps. So it's PDD9520805292.

But it says, "Rationale for Another Controlled-Release Opioid Analgesic: MS Contin may eventually face such serious generic competition that other controlled-release opioids must be considered. Other pharmaceutical firms are thought to also be developing other controlled-released opioid analgesics."

MR. STRAUBER: Mr. Thompson, if you're reading from a document, could you show it to the witness?

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MR. THOMPSON: Sure. That's why I was holding it over here.

MR. STRAUBER: It's hard to read from that distance.

MR. ELLIS: Here's an extra copy.

MR. THOMPSON: Great.

MR. STRAUBER: Do you have a copy for me, also?

MR. ELLIS: (Passing document.)

MR. STRAUBER: Thank you.

Q. So do you see down there the second highlighted portion that says "Rationale."

A. Mine is not highlighted.

Q. Yeah. I'll tell you where to go.

A. Okay.

Q. So the second highlighted portion, "Rationale for another controlled-release opioid analgesic." And do you see the first sentence below that?

A. Oh, I see. That's a cross-title.

Q. Yes.

A. I was looking at the text.

Q. And the text below that says, "MS Contin may eventually face such serious generic competition that other controlled-release opioids must

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be considered. Other pharmaceutical firms are thought to be -- to also be developing other controlled-release opioid analgesics."

Did I read that correctly?

A. You did.

Q. And was that a concern at that time?

A. It was a secondary or tertiary driver.

Q. And then if you'll turn to the next page and look at the second paragraph. And I'll read that. It says, "While we have reason to believe that other pharmaceutical firms are formulating controlled-release morphine and controlled-release hydromorphone, there is no evidence to date that this is being done with Oxycodone. A controlled-release Oxycodone is, thus, less likely to initially have generic competition."

Was that a consideration when deciding to come out with Oxycodone -- or OxyContin?

A. Not for me.

Q. All right. Now, we read your paragraph 11 where you discuss that you had limited role in the --

MR. DANFORD: Do you have a copy of that so he can take a look at that?

MR. THOMPSON: Yes. Paragraph 11.

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(Passing document.)
Let's make this Exhibit 1 to the deposition.
(DEPOSITION EXHIBIT NO. 1 MARKED)
Q. And this declaration said that you were not directly involved with the day-to-day marketing or promotion of OxyContin, the training or management of Purdue sales representatives, or the scientific research into the conversion ratio of MS Contin to OxyContin. Is that correct?
A. That is correct.
Q. I want to show you an e-mail. Let's mark this Exhibit 2 to the deposition.
(DEPOSITION EXHIBIT NO. 2 MARKED)
A. I need to just clarify. I'm emphasizing "directly involved." I didn't do any of the work. I didn't do any of the training. I was not a salesperson.
Q. Okay.
A. But as a senior executive, I certainly was aware of what was going on and I consulted with other senior executives about what was going on and what should be going on and so on.
Q. Okay. And then this e-mail that was just handed to you a few moments ago says -- again,

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it's Cornelia Hentzsch. It's dated May 29th, 1999. It says -- if you'll read the highlighted portion. It says -- this is an e-mail from you to her, correct?
A. Yes.
Q. It says, "You won't believe how committed I am to make OxyContin a huge success. It is almost that I dedicated my life to it. After the initial launch phase, I will have to catch up with my private life again."
Did I read that correctly?
A. You did.
Q. When you say you dedicated your life to it and that you have no time for your private life, what were your day-to-day activities with respect to OxyContin?
A. May I read the -- the whole document? I haven't seen this for 16 years.
Q. Have you read your deposition in the Endo litigation?
A. No. In preparation for this?
Q. Yes.
A. No.
The context of this was to encourage Dr. Hentzsch, who was the head of the Australian business and was meeting with great success with

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MS Contin, to pay perhaps more attention than I thought she was paying to the prospects of potential for OxyContin. So this was in the spirit of motivating her.
It was true that I was very gladdened to see that OxyContin was meeting with so -- with such a strong positive reception by both physicians and patients, and I was working hard at the business. But it -- if you -- you would misinterpret this if you thought that I was working only on OxyContin. That was not the case.
Q. Okay. When you say you were encouraged by the number of physicians that were selling it --
A. Prescribing it.
Q. -- prescribing it, you were not aware at this time, were you -- or were you aware -- that your company was committing a felony in how they were marketing and branding the drug?
MR. STRAUBER: I object to the form of the question.
A. I was not aware at all of what you're saying. And when I say I was heartened by physicians' reception, when I did speak to physicians at meetings -- I didn't go on sales calls -- but at some

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meetings and conferences, they were extremely enthusiastic about the effectiveness and the safety and the reception their patients had, the response they had to the product. That was what I was referring to. Because, as I had told you before, our goal was to make a better product than MS Contin, and I believe we -- this was one of the ratifications of that.
MR. THOMPSON: Let's mark this Exhibit 3.
(DEPOSITION EXHIBIT NO. 3 MARKED)
MR. STRAUBER: May I have a copy?
MR. ELLIS: You already have it.
MR. STRAUBER: The witness has it. I'd like to have a copy.
MR. ELLIS: I think you have it in front of you and your hand is physically on it.
MR. STRAUBER: You tell me. I don't see it.
MR. ELLIS: You're holding it.
MR. STRAUBER: I'm holding 1 and 2.
MR. ELLIS: That e-mail that you have your hand on. We may have just marked it twice. That may be the problem.
MR. STRAUBER: You've marked it twice.

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3 and 2 are the same?
MR. ELLIS: Yeah.
MR. STRAUBER: Okay. Then I have it because I have 2.
Q. And we'll get into this a little more later on, but you're aware that Purdue pled guilty to a felony charge of misbranding a drug, which was OxyContin, with the intent to defraud or mislead? You are aware of that, correct?
MR. STRAUBER: That is Purdue -- that is -- pursuant to your earlier statement, that is Purdue Frederick; is that right?
MR. THOMPSON: Yes.
MR. STRAUBER: Okay.
A. Okay. So when you said "Purdue," you meant Purdue Frederick?
Q. Purdue Frederick Company, Inc.
A. Yes, I am aware.
Q. Did you -- is it your understanding that the fraud only occurred with respect to the Purdue Frederick Company and not with respect to Purdue Pharma, L.L.P.?
A. That's my understanding. But I'm not an attorney and that's a very deep legal question.
Q. Did you do any investigation to find

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out whether sales reps employed by Purdue Pharma were exceeding what they were allowed to do when they were marketing, that they were making claims that were untrue?
MR. STRAUBER: Objection to form. He can answer.
A. When you say "you," are you referring to me personally or are you referring to the company?
Q. I'm referring to you personally.
A. I did not conduct or manage any investigation. But from the time we learned at top management levels that there was an abuse and diversion program, which was years before the settlement with the government, we launched multiple investigations both with inside resources and people and with external attorneys and others to identify -- and this was before any charges were made -- to identify if we had in any sense mislead or caused this to happen.
More important, we spent enormous resources to try to mitigate the problem whatever the cost was, and that effort, which was launched sometime in 2000 or 2001, continued right through the period that you're referring to of the plea with the U.S. government.

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Q. And did you-all launch this investigation as soon as you learned there was a problem?
A. Yes. Within -- within months or weeks. I can't recall. It was 16 -- 15, 16 years ago.
Q. Do you -- who is Michael Friedman?
A. Michael Friedman is the -- was at that time the head of sales and marketing.
Q. Have you seen his presentation At Purdue that he -- do you know what At Purdue is, your-all's internal newsletter that goes out to all the employees?
A. I don't believe I saw a presentation At Purdue from him.
Q. All right. We'll get to that later. This is a memorandum dated July 15th, 1992, "Meeting with Shionogi held Wednesday July 24th, 1992" from Dr. J.W. Watkins, and there's a distribution list. I'll assume you are Dr. R.S. Sackler; is that correct?
A. That would be me.
Q. And if you would turn to page 6 of this document that is PDD1701546226. And to give it a

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little context, Shionogi, is that a Japanese company?
A. It is.
Q. And at one time were you-all talking about doing some sort of business with them involving potentially OxyContin Controlled-Release?
A. Yes.
Q. And did you do business with them involving OxyContin Controlled-Release?
A. Yes.
Q. Let's look at page 6, if you would, the -- it looks like maybe the third paragraph down that begins with "Dr. Kaiko..." Do you see that?
A. Yes.
Q. "Dr. Kaiko presented two options identified for positioning OxyContin AcroContin..." Now, is that the controlled-release?
A. That was our working title of the controlled-release system.
Q. "...versus MST Contin Tablets in the U.S. The first was relevant if PF" -- who is PF?
A. Purdue Frederick.
Q. -- "did not suffer substantial erosion of its MS Contin market by generic competition. This envisioned using Oxycodone AcroContin Tablets over the entire spectrum of pain in patients whose treatment

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had been initiated with this product, whilst MS Contin Tablets would be used as therapy for chronic severe pain in patients who were changed from other medication including Oxycodone AcroContin Tablets.

"An alternative scenario would apply if MS Contin Tablets were subject to erosion by generic competitors. In this case Oxycodone AcroContin Tablets would be promoted for use across the entire pain spectrum, including those patients who might otherwise receive controlled-release morphine."

Did I read that correctly?

A. You did.

Q. Okay. And was it your intent to promote OxyContin Controlled-Release across the entire pain spectrum?

A. Where? You're referring to Japan, which is where Shionogi either had or was negotiating a license for OxyContin.

Q. Was it also your intent in the U.S. to promote it across the entire pain spectrum?

A. It was our hope that it would be well-received for pain -- moderate to severe pain requiring opioids.

MR. THOMPSON: Let's mark this as Exhibit 4.

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(DEPOSITION EXHIBIT NO. 4 MARKED)

Q. And here is PDD9524706426, OxyContin launch team memo dated 3-31-95.

And OxyContin was actually launched in January of '96; is that correct?

A. That sounds correct.

Q. And what this says -- if you will turn to page -- first of all, let me ask you this.

Do you recall having any significant problem with MS Contin with respect to addiction, abuse, diversion or any of the problems that you experienced with OxyContin CR?

A. I -- I recall never hearing about that.

Q. All right. So let's look at page 2, the last paragraph. It says, "Our meeting ended with a question and comment period. Michael Friedman emphasized the threat that AB-rated generics posed to MS Contin. We're not sure when AB-rated generics will be launched, but we don't think it will be until 1996. Inevitably, AB-rated generics will arrive, and this is why it is of extreme timely importance that we must establish OxyContin. OxyContin can cure the vulnerability of the AB-rated generic threat, and that is why it is so crucial that we devote our fullest efforts now to a successful launch of OxyContin."

Did I read that correctly?

A. You did.

Q. And who is Lydia Johnson?

A. I don't know.

Q. This department, it looks like it's the marketing department; is that right?

A. I just see a distribution list. I don't see a source. I don't know -- it says that the department is marketing, but I don't know Lydia Johnson.

Q. Was it your belief that it was of extreme timely importance that OxyContin be established because AB generics were going to arrive and compete with MS Contin?

A. No.

Q. All right. Let's mark this as Exhibit 4.

MR. STRAUBER: We already have a 4.

MR. THOMPSON: Then this would be 5.

(DEPOSITION EXHIBIT NO. 5 MARKED)

Q. Dr. Sackler, do you know how much money to date has been generated by the sale of OxyContin?

A. I don't understand the question, money generated.

Q. How much money has Purdue Frederick or Purdue Pharma made off the sale of OxyContin?

A. I don't know.

Q. There was an article last month in Forbes. "The OxyContin Clan. The 14 Billion Newcomer to Forbes 2015 List of the Richest U.S. Families."

Have you seen that?

A. I have seen it once.

Q. Do you know what percentage of Purdue Pharma sales is made up of OxyContin?

A. Presently?

Q. Yes.

A. Approximately two-thirds.

Q. I've looked at the --

A. That's Purdue Pharma's sales.

Q. Sales. Purdue Frederick does not sell anymore, correct?

A. No.

Q. You've got another -- a number of other entities that generate income from the sale of OxyContin, correct?

A. Overseas.

Q. Yes. And do approximately 90 percent of the profits of the company come from OxyContin?

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MR. STRAUBER: Question. "The company"? You're referring to now Purdue Pharma?
MR. THOMPSON: Purdue Pharma.
A. I don't believe it would be 90 percent, but it is certainly a majority.
Q. Do you currently make over a billion dollars a year selling OxyContin?
MR. STRAUBER: Objection to the form. By "you," now you're talking about Dr. Sackler?
MR. THOMPSON: Yes.
A. No, I don't.
Q. All right. Does Purdue Pharma make over a billion dollars a year?
A. I'm not sure. I don't think it would be that much.
Q. Let's talk about gross sales. Are gross sales over 3 billion dollars a year?
A. No, they're not.
Q. What are the gross sales?
A. Well, I think what you're looking for is net sales. Because in the industry a lot of money is inherently rebated back to purchasers, insurance companies, hospitals, et cetera, through wholesalers in rebate agreements, which are negotiated. So I

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believe the net sales are in the range of, this year, a billion dollars.
MR. STRAUBER: Your question was directed to Purdue Pharma?
MR. THOMPSON: Purdue Pharma.
A. Right.
Q. Are there any other Purdue entities that make money that would not be included in that one billion dollar sales?
A. Not --
MR. STRAUBER: Objection to the form of the question.
You can answer.
A. Not in the United States.
Q. Do you know how much the Sackler family has made off the sale of OxyContin?
A. I don't know.
Q. But fair to say it's over a billion dollars?
A. It would be fair to say that, yes.
Q. Do you know if it's over 10 billion dollars?
A. I don't think so.
Q. Do you know if it's over 5 billion dollars?

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A. I don't know.
(DEPOSITION EXHIBIT NO. 6 MARKED)
(Passing document.)
Q. This appears to me -- what's been marked as Exhibit 5, it's PKY --
MR. ELLIS: 6.
Q. 6, I'm sorry. Exhibit 6, PKY1738172006, appears to be a profit calculation for a Purdue entity. Can you tell me which entity that is?
A. If it's not on the document, I couldn't possibly tell you.
Q. Did Purdue Frederick still exist in 2006?
A. I'm not clear. I think it did.
Q. This appears to be a profit calculation for OxyContin Tablets only. Do you see that?
A. I do.
Q. And it appears that at least by 2006 profit contribution was 4 million -- 4,718,767,000. Is that correct?
A. You've read the number correctly, but profit contribution is not profit.
Q. And what would you subtract from that?

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A. All of the money that was invested in the business to develop new products. That would be a major deduction from that.
Q. Let's mark this -- well, let's -- you're right, I think it is. Look up at the top where it says, "Gross profit 7,502,367,000."
A. Just a second. Small type. Just a second. "Gross Profit." I see "Gross Sales." I see "Rebates," and then "Net Sales." Okay, I'm with you on "Gross Profit."
Q. Okay. So deducted from that is shipping, warehousing. You have 536 million paid to Abbott for co-promotion commission?
A. That's correct.
Q. You have an S&P expense. What's that?
A. Sales and promotion.
Q. All right. That was 141 million on sales and promotion; is that correct?
A. That's correct.
Q. R&D expense, 308 million?
A. Right. And I'm looking for the number. I'm sorry.
Q. Sales force.
A. Yes, I see that. But can I explain?

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That's the R&D associated with the product.
Q. Right.
A. Not the R&D for other products.
Q. Right. And then sales force is 960 -- or 87,222,000 that they've been paid?
A. That's what it says.
Q. And then it's got a G&A expense. What is that?
A. General and administrative.
Q. All right. 492 million?
A. Yes. Over how many years? '96 to 2005. So it's nine years. Am I counting correctly?
Q. You are.
Then there is product liability and patent litigation expense. You had OxyContin litigation expenses. Then you have profit after all those are subtracted on OxyContin of 4,718,000,000. Is that correct?
A. That's what it says. I can't testify that that's correct, but that's what it says.
MR. THOMPSON: Let's mark this as Plaintiff's Exhibit 6. I think we've already marked it.
MR. DANFORD: We've been going about an hour.

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MR. THOMPSON: I try to go a little bit longer. I mean, if you all need a break, we can take a break, but...
THE WITNESS: I need to take a break.
VIDEOGRAPHER: We are off the record at 10:06 a.m.
(RECESS)
VIDEOGRAPHER: We are back on the record at 10:18 a.m.
BY MR. THOMPSON:
Q. All right. Dr. Sackler, I want to ask you about one more thing in Exhibit 4.
(Passing document.)
And if you look at the second paragraph, there's a comment that says, when discussing Oxycodone AcroContin, which is controlled-release Oxycodone --
A. I'm sorry. Just -- page what?
Q. The first page, second paragraph.
A. Okay.
Q. It says, "The molecule lacks the stigma of morphine and may be of particular advantage in the five percent, approximately, of patients who cannot be adequately treated with morphine."
Was it your understanding that

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approximately 95 percent of the patients out there could be treated with MS Contin?
A. No.
Q. Do you disagree with that statement that --
A. I do. I disagree.
Q. What percentage do you think of patients could be adequately treated with MS Contin?
A. Between 50 and 75 percent.
Q. And what studies are you basing that on?
A. I'm basing it on general experience of being involved with MS Contin and OxyContin since 1980.
Q. Did you ever do any studies to determine what percentage of patients could be adequately treated with MS Contin?
A. I don't remember any.
Q. Okay. Did you ever do any studies on abuse liability for OxyContin before you-all put it on the market?
A. I'm not aware of any.
Q. Let me show you what's been identified by Bates stamp PDD8801123847. We'll mark this Plaintiff's Exhibit 7.

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(DEPOSITION EXHIBIT NO. 7 MARKED)
Q. And I'll ask you if you can identify this?
(Passing document.)
MR. STRAUBER: May I have a copy?
MR. ELLIS: I'm getting one.
(Passing document.)
MR. STRAUBER: Thank you.
Q. And does this appear to be a memo to you from Paul Goldenheim?
A. It is.
Q. And who is Paul Goldenheim?
A. At the time he was head of Research and Development.
Q. Okay. And just to kind of walk through this memo. From the bottom down there, it looks like you had sent a memo on March 14th of '97 to a number of individuals at --
A. I'm looking for that. I'm looking for my -- oh, from me. Okay. I see that. Okay. I'm sorry. I see now. It's two e-mails. Okay. Thank you.
Q. And the paragraph at the bottom says, "The BfArM," what is that?
A. That was the German regulatory agency

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at that time.

Q. It says, "Were asked whether OxyContin to be classified as a controlled drug or whether it would be possible to obtain a relaxed status because of the difficulty in extracting Oxycodone from the matrix and the fact it was less liable to abuse because it was unknown."

So just dialing down on that first sentence, you were wondering whether Oxycodone could be less regulated in Germany; is that correct?

A. I believe that I was reporting something to Paul that I must have heard, but I was not involved in making any discussions or meetings with BfArM.

Q. Okay.

A. Can I -- may I just read the rest of it if we're going to continue on this?

Q. Sure. I'll tell you what, I'll read it to you.

The next sentence says, "The BfArM" -- B-f-A-r-M -- which I understand is the German regulatory authority?

A. That's correct.

Q. -- "answered that unfortunately OxyContin would definitely be classified as a

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controlled drug for all strengths as is morphine. There could be no exception because of the controlled-release protection because there had been a few reports of abuse and there were limited data on long-term use."

Did I read that correctly?

A. You did.

Q. Okay. And then you have here in caps, "We have a lot of use data in the U.S. with very, very, very few ADEs."

What are ADEs?

A. Those are reports to the agency, to the FDA. And ADE stands for adverse drug experience. All adverse drug experiences are reportable to the agency. Anything we are aware of we must report periodically. Anybody else, however, can also report ADEs to the agency. And so the agency maintains a catalog for every drug of ADEs.

Q. And then you have in caps, continuing, "We can run another long-term trial to get more data, and if the abuse potential is equal or lower than with another nonscheduled drugs, would BfArM unschedule it?"

That's your question, correct?

A. That was a question.

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Q. And then Dr. Goldenheim writes back on the subject of "Is this an opening to descheduling the agent?"

And descheduling means make it less restrictive, correct?

A. That -- that's how I would understand it.

Q. And if it's less restricted, would you think that you could sell it to more people?

A. It would be easier for physicians to prescribe it.

Q. It's going to increase sales?

A. That is reasonable because they could prescribe it -- if it were Schedule III instead of Schedule II, as are some drugs, physicians could prescribe by telephone.

Q. And his response is, "We do not have any abuse liability studies."

And this is as of 1997, correct?

A. That's correct.

Q. To date have you done abuse liability studies?

A. Yes; many.

Q. When were they done?

A. I don't know when the first ones were

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done, but they were done repeatedly for many formulations subsequently of both Oxycodone and of other abusable opioids, both in controlled-release form and in immediate-release form.

Q. Have you done abuse liability studies for OxyContin Controlled-Release?

A. I don't -- yes, the new -- the new formulations definitely.

Q. And when were those done?

A. I don't know exactly. But before the products were submitted to the agency.

Q. You're saying the new formulations?

A. The new formulation.

Q. When were the new formulations submitted?

A. I'm doing this from memory now. About 2008.

Q. Okay.

A. But I could be in error by a year or two.

Q. So by 1997, two years after this product was on the market, he says, "We do not have any abuse liability studies. I think this is a dead end. Adding naloxone, I think, is the only possibility, but this is a difficult project from the

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clinical perspective. We are investigating for Oxycodone."

Was that his response?

A. That is what he wrote.

Q. He's basically saying they're not going to deschedule this?

A. Unless -- perhaps they might if it incorporated naloxone.

Q. And naloxone is an additive?

A. It is -- it is a reversal agent. It blocks the effect of opioids.

Q. And you-all did not incorporate naloxone, correct?

A. We subsequently did in some markets. In Europe in particular and to some extent elsewhere.

Q. Did they require you to do that?

A. No. We did it for another reason.

Q. What was the reason?

A. We discovered that it did not block the effect of the opioid apparently at all, but it did reduce the gastrointestinal side effects dramatically, including constipation, which is the most common side effect for any opioid.

I could add that by the time we had a full press to develop an abuse-resistant form of

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OxyContin we did do extensive work with another antagonist called naltrexone, and naltrexone did, when it got released, block the effect of the opioid. But, unfortunately, after a huge investment, we could never be certain that it wouldn't be released when it was taken orally. It was almost perfect, but it had to be perfect because the agency said that if it released and blocked the effect of the opioid in patients, they would not approve it and we could not reach perfection.

Q. Let me show you an e-mail chain that's been produced. I'll mark this.

(DEPOSITION EXHIBIT NO. 8 MARKED)

Q. It's PDD29520806439. And if you start at the back, I believe, this e-mail chain begins at the back. And this is an e-mail from you dated -- the last e-mail is the first e-mail, and it's dated 3-2-97.

A. Wait. I'm seeing 3-11-97. It's sort of a little out of order, isn't it?

Q. I'm sorry, yeah. There is -- mine tore off.

A. Oh, no, 3-12-97.

Q. 2-12-97 is the first.

MR. ELLIS: I've highlighted it for

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you, Dr. Sackler.

THE WITNESS: Pardon?

MR. ELLIS: I've highlighted your e-mail.

A. 2-27. It's not -- oh, it's the middle page for me, not the last. Okay. Yep.

MR. DANFORD: Can we organize those?

MR. STRAUBER: Yeah, I'm not sure that all the pages have been assembled properly.

MR. ELLIS: These are the -- this is the way this document was produced to us. The reason that there's a skip in the Bates range from the last two pages is because Purdue produced a totally random document in between it. But if you look at the Bates numbers of the original Bates stamp on this document, they're consecutive among those pages in a consecutive e-mail chain.

So I have taken the liberty of removing the completely erroneous page that has nothing to do with this e-mail chain and produced it to the witness.

MR. DANFORD: My question is not about that. The question is if he has a different formulation.

MR. ELLIS: No. He's got the same

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document.

MR. STRAUBER: Exactly. We're just trying to make sure that we're all working from the same document here.

Q. So if you'll go to the 2-27-97 e-mail.

MR. STRAUBER: That's it (indicating).

A. I had to look for it. I expected it at the end, but it wasn't. Okay. Yes.

Q. It says -- this is from Walter Wimmer at Mundipharma-Germany.

And that's a company that's owned by the Sackler family, correct?

A. It is.

Q. And who is Walter Wimmer?

A. He was the general manager at that time.

Q. And he says, "Dear Bob." First paragraph. "In the course of this conversation he explained to you that due to his discussions with BfArM he does see a 50 percent chance to get OxyContin off the narcotic drug status provided you could give some information on the very low abuse potential of our CR formulation."

Did I read that correctly?

A. You did.

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Q. And then in response to that, if you go up to the top, Dr. Robert Kaiko has an e-mail dated 2-27-97.

A. He does.

Q. And he says, "While my thinking is still developing, frankly, I'm very concerned, and I would have to recommend against the uncontrolled but monitored proposal at this time. (Perhaps if only to make sure the risks are appreciated and accepted before we proceed as proposed)."

Do you know what risk he was discussing?

A. I have no idea.

Q. Did you ever discuss with him why he was recommending against going uncontrolled but monitored with respect to OxyContin?

A. I don't even know what it means.

Q. All right.

A. If I read the rest of it, do you think it would give me a clue or -- I infer that because you didn't highlight it, you don't think it would shed any light on what was meant above?

Q. Well, let's read the rest of it. It might help. He says under paragraph B, "I don't believe we have a sufficiently strong case to argue

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that OxyContin has minimal or no abuse liability."

This is dated 1997, correct?

A. Yes.

Q. He says, "In the U.S. Oxycodone-containing products were once less controlled than now. Abuse resulted in greater controls."

Is that accurate?

A. I believe it is.

Q. And what he's saying there is, these weren't as controlled at one time and they got abused, and that's why we have controls now, correct?

A. I believe that is the case.

Q. He says, "Oxycodone-containing products are still among the most abused opioids in the U.S. This information is available to BfArM, the German regulators."

A. I -- that's certainly true that the information would be available to them.

Q. And he says, "The local tissue necrosis that can result from injection of OxyContin 'fixed' for such abuse is not likely to be a deterrent to abuse. Let us not forget that in New Zealand MST is the most common sources of parenterally abused morphine/heroin."

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Were you aware at that time that OxyContin -- there was a concern that Oxycodone opioids could be injected or abused?

A. I don't remember this memo and I don't remember whether I had read the whole chain carefully or not or even saw it.

Q. Then he says, "Our dossier acknowledges" -- by "dossier," I assume he means the documents --

A. Yes.

Q. -- Purdue has?

A. Yes.

Q. "Our dossier acknowledges a small handful of patients in our research program" -- and that means studies you-all were doing; is that correct?

A. That's -- that's what I would understand it would mean.

Q. -- "who were suspect in terms of their drug accountability."

Do you know if that was reported to anyone, that your-all's dossier had a handful of patients who were suspect in terms of their drug accountability?

A. I don't know if it was reported, but

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I'm confident it was. If it was an FDA-submitted trial, it would have been in either the safety summary or the -- or the efficacy summary, or both.

Q. Do you remember the issues with the Roth reprint where there were patients who they determined had withdrawal symptoms and that was not reported?

MR. STRAUBER: Objection to form.

A. No. I'm sorry.

Q. Are you familiar with the Roth reprint?

A. No.

Q. Do you know whether that was part of the plea agreement that Purdue Frederick had when they pled guilty to a felony?

A. I don't -- I don't recall.

Q. And it says under paragraph C, continuing on, "We do not" -- "We do not have a post-marketing abuse monitoring system and database from which we could conclude that diversion abuse is not occurring."

Were you aware that you-all put this on the market, OxyContin CR, and did not have a post-marketing abuse monitoring system or database from which you could tell whether abuse or diversion

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was occurring?

A. I was not aware of that. I don't believe it was a requirement at the time. I'm sure we would have fulfilled all the FDA requirements that they asked us.

Q. Do you think it would have been a good idea before putting OxyContin Controlled-Release on the market to have an abuse monitoring system and database from which to tell if it was being diverted or abused?

A. Absolutely, yes.

Q. And then under paragraph C it says, "If OxyContin is uncontrolled in Germany, it is highly likely that it will eventually be abused there and then controlled. This may be more damaging to OxyContin internationally than any temporarily higher sales that could be gleaned from an uncontrolled status. Let us not forget the experience with buprenorphine, which was initially uncontrolled. Reports of abuse in Germany in part eventually led to lots of bad press and controlled status. Worldwide sales suffered even where buprenorphine had already been controlled. So, given the above, what do others have to offer that should prompt us to pursue the proposal for uncontrolled status for OxyContin

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anywhere?"

And was that the response of Robert Kaiko?

A. It appears to be so.

Q. And who was Robert Kaiko?

A. He was in charge of the development program of OxyContin.

Q. Was he the chief medical officer?

A. No. But he was -- he was respected. His opinions were respected and were heeded.

Q. And then the next e-mail, which comes from you, is Dr. Richard Sackler at Norwalk.

A. Give me just a little time to find it since they're not in order. Okay, Norwalk. And could you read the date, please?

Q. It looks like it's 3-2-1997.

A. 3-12. 3-12-97?

Q. I'm looking at 3-2. It says 02-03-97, but I think the way it's computed, it's really March 3rd.

A. Okay. I see something from 3-12. I see something from 11-3-97.

Q. It's page 5. Maybe that will help.

A. Oh, I don't think I have page -- oh, page 5. Okay. Thank you.

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Q. And this is your response to Robert Kaiko saying this is a bad idea for all these reasons. And you say, "This is the first time I've heard of this idea. What makes us believe that we can accomplish it, Walter? How substantially would it improve your sales?"

And what you're talking about there is if we can get it uncontrolled in Germany, how substantially will it improve sales, correct?

A. Yeah. Yes, that was -- it would appear that that's what my question was.

Q. "Please give a five-year projection with control and without. Does each member of the EU" -- is that the European Union?

A. Yes.

Q. -- "decide this for themselves or would one lead? If one would lead, then is Denmark or Germany more likely to agree?"

And then Harry Kletzko of Mundipharma writes you back on March 7th and says, "Dear Dr. Richard" --

A. Just a second. Now we're on page 1 or 2?

Q. That's the same page. The one right above.

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A. Okay.

Q. "Please find stated below our five-year projection of OxyContin without and with controls as requested."

A. Uh-huh.

Q. And it was projected that with first year non-narcotic -- narcotic drug with control would be 3.000 TDM. Do you know what that is?

A. I assume total or something Deutschmarks. Something Deutschmarks.

Q. And that would be 3 million?

A. That would be my understanding.

Q. And then turnover non-narcotic drug without control is 10 million?

A. The first year.

Q. The first year. And on the fifth year it was projected to be 18 million with control but 30 million without control, correct?

A. That's what it says.

Q. And then you wrote back on 3-8-97, right above that one, and it says, "BK advised that the regulatory authorities did say" --

A. RK. BK. I'm sorry. I heard DK.

Q. -- "advised the regulatory authorities said that Oxy would be scheduled and so it would be

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under narcotic control. Does this correspond to your info? If so, is this matter now closed or is there some appeal or other procedure you would want to consider?"

So you still saw the advantage of getting OxyContin CR uncontrolled and were wondering if there was some way you might appeal the German decision?

MR. STRAUBER: Objection to form.

That's not what the statement says that you just read.

Q. Well, correct me if I'm wrong there. Why did you say is there some appeal or other procedure you want to consider?

A. Okay. This whole experience is actually like reliving a third of my life, and I had completely forgotten, until I saw this document, that Walter had been very hesitant to pursue the development or the marketing of OxyContin because he didn't believe it would sell very well. He turned out to be completely wrong and when it was introduced it did extremely well.

We were of the contrary opinion, but he said -- he came back and he did quite a bit of work without any reference to anybody else on determining or trying to get the BfArM to consider not scheduling

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it. And this whole stream was occasioned by that. We -- many of us in the U.S. were not enthusiastic about not scheduling it.

In Germany there is no equivalent, at least at that time that I recall, of anything like Schedule III. You are either an abusable drug and, thus, you had all the abusable drug controls or you were not. And we were not in favor of this, but we were trying to be polite and solicitous rather than saying, this is a terrible idea, forget it, don't do it. Because we still felt that with the controls, which we thought would be appropriate and were appropriate obviously, it would still be very welcome, very useful to patients in the German market.

So this whole stream -- this whole trail really was occasioned by that. But I don't remember anymore. So if we go on, I'm going to relive another few days of my life.

Q. Sure. Let me ask you. If you thought controls were appropriate, why were you asking here or raising the issue if there was some appeal that could be taken with regard to the --

A. Just to be polite, not to just shut him down.

Q. Okay. Well, let me ask you this.

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Let's go to the next one, which is page 4. He writes back, "Yes, Richard, this does correspond to the information given by Mr. Goerich, our registration officer. We also attended the meeting with the BGA. This matter is now closed. There is no way of appeal."

Is that what he told you?

A. That seems to be what he told me.

Q. And then you wrote back and said, "When we are next together we should talk about how this idea was raised and why it failed to be realized. I thought that it was a good idea if it could be done."

Was that your response to --

A. That's what it said, but I didn't mean it. I just wanted to be encouraging. I was very glad it was closed.

Q. Up at the top there's a note -- there's another response from Walter Wimmer who says, "To get the product off narcotic drug status, it would be possible to combine Oxycodone with naloxone provided the development costs weren't too high." That was sent on 3-12.

A. Okay. Let me --

Q. And then the top one is cut off, but

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it says, "Paul, Michael. Would this be a feasible approach here in the U.S.? I don't know of any C-II narcotic that is de-scheduled when naloxone is added, do you?"

Was that a question you were raising?

A. It looks like I raised it just as a matter of information. As I said, they eventually did develop that product and it was extremely successful. At the time they researched it, they quickly discovered that naloxone didn't achieve the desired blocking effect, but they made another discovery that was even more valuable.

Q. Would I be correct that Purdue Pharma never conducted or retained anyone to conduct studies regarding addiction and physical dependency rates of Oxycodone products at least as of March 4th, 2002?

A. I don't know the answer.

Q. Are you aware that counsel for Purdue Pharma's answer to interrogatories that requested the names of all individuals retained by Purdue Pharma to do studies regarding addiction and physical dependency rates of OxyContin products and copies of all studies, and he answered, "We never conducted or retained anyone to conduct studies regarding addiction and physical dependency rates of Oxycodone products."

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MR. STRAUBER: Mr. Thompson, if you're reading from a document, could you show it to the witness?

MR. THOMPSON: No. I'm just asking if he's aware of it because I'm trying to move the deposition along.

Q. So are you aware of that?

A. No, I'm not aware of his -- his statement.

Q. Are you aware of any studies conducted or retained -- or anyone being retained to conduct studies regarding addiction and physical dependency rates of Oxycodone products prior to 2002?

A. I'm not aware of any or don't remember any. In 2002 I was the president of Purdue Pharma, and this would not have necessarily -- this wouldn't have required my approval or knowledge unless it was -- it led to something that was surprising or important and unexpected.

MR. STRAUBER: Mr. Thompson, did you put an -- give an exhibit number to the last document that we were discussing, which was a series of e-mails?

MR. THOMPSON: It was 8.

MR. STRAUBER: 8. Okay. Thank you.

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(Passing document.)

Q. All right. I'm going to switch and ask you a little bit about the OxyContin Project Team. And this is a memo dated December 14th, 1993, PDD9520509356. There's a few paragraphs I want to try to cover here.

If you will look at the bulletin points on the front page, the second one from the bottom says "Marketing: OxyContin Tablets will be marketed against Percocet and Duragesic. The OxyContin line may replace our MS Contin line if MSC generics are competing." Is that correct?

A. That's correct.

Q. And that's not the -- is that the malignant cancer group of patients, or is that the non-malignant cancer group of patients?

A. I'm sorry?

MR. STRAUBER: Objection to the form.

I don't understand the question.

Q. Go ahead, you may answer.

A. MS Contin, as I said before, was used in treating both cancer patients and non-cancer patients and there was no focus, I don't believe, or consideration in this statement of whether it would be both, I think.

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Q. Do you have a knowledge of what Percocet and Duragesic was used mostly to treat?

A. Percocet and -- Percocet was an extremely widely used product used to treat both short and long-term pain conditions, both non-malignant and malignant.

Q. And then, if you'll turn over to paragraph 2.3. And this says 1993. It says, "Abuse Toxicity Bench-Top Study - The results of a spoon" --

A. Okay. I see. 2.3 you said?

Q. Yes.

A. Thank you.

Q. -- "The results of a 'spoon & shoot' study have been sent to the FDA."

What was a 'spoon & shoot' study?

A. I don't know. I could guess, but I don't know.

Q. Was that a study done to determine if the drug could be abused by extracting Oxycodone from the tablet?

A. It's a reasonable guess, but I don't know the details of what that study was.

Q. And then under 3.2, the last sentence says, "A crushed tablet study may be conducted if we decide such a study is needed."

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Do you know if you ever decided such a study was needed?

A. What's the number on that? I'd just like to read it.

Q. 3.2, the last sentence.

A. I'm sorry. Thank you. 3.2?

Q. Uh-huh.

A. Yes. Okay, I've read that.

I don't know if such a study was done.

Q. And then on 5.4, the very last sentence says, "Mike Innaurato." Was he a guy in charge of marketing?

A. No. He was -- he worked in the marketing department, but he was not -- at this time he was not in charge. He was a middle manager of marketing.

Q. All right. It says, "Mike Innaurato asked if we had any quality of life questions in our ongoing studies. Robert Reder stated that we did not, but that we could include quality of life questions in future studies."

Do you know if quality of life questions were included?

A. I believe there were studies later that included quality of life measures, but I am not

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certain of that. I am certain it would have been favorable, but I'm not certain just what studies were or were not done.

MR. THOMPSON: Let's mark that as -- has it been marked yet?

COURT REPORTER: No. 9.

MR. THOMPSON: -- Exhibit 9.

(DEPOSITION EXHIBIT NO. 9 MARKED)

Q. With respect to Oxycodone and morphine, do you know whether OxyContin is more powerful or less powerful a drug than morphine?

A. It depends what you mean by "powerful."

Q. I think Dr. -- is it Goldenheim?

A. Yes.

Q. Was he an employee of --

A. Yes.

Q. I think he testified that -- that Oxycodone was twice as strong as morphine. Is that your understanding?

A. If the question -- if powerful means potency, absolutely, it is twice as potent as morphine. And we were very proud that we discovered this, first in animal studies and then in human studies, and we made it widely known perhaps even

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before the drug was introduced, but certainly in the package insert and all the promotional material.

Q. Do you know how many doctors or what percentage of doctors thought that it was equal to or less strong than morphine?

A. I would assume very few if they -- if they were promoted to. I can't believe that they wouldn't have understood that. That formed the basis of our recommendations of dosing of the strength of the tablets that were developed. And, in fact, it was consistent with physicians' own experience with Percocet where they would administer a 5-milligram dose and they -- if they used morphine, they knew that 5 milligrams of morphine would achieve very little pain relief if given orally, perhaps somewhat more if given by injection.

MR. THOMPSON: Let's mark this as Plaintiff's Exhibit 10.

(DEPOSITION EXHIBIT NO. 10 MARKED)

(Passing document.)

Q. This is the memo dated 1992, August 10th, Oxycodone Project Team Meeting Minutes.

A. I'm sorry, August 10th.

Q. And it is PDD9521410329.

A. 39? I have 30. The first page is 39.

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Q. Correct. And if you'll look at this, it says, "A literature search" -- the second paragraph. "A literature search on oxycodone and oxymorphone is being conducted" --

A. I'm sorry. It's just not very clear. Give me a second. "A literature search" -- are we looking at the same page?

Q. No, we're not. You're on page 2, I'm on page 1, second paragraph.

A. I'm sorry. I thought you said August 10th. This one is August 4th. Okay. I'm sorry.

Q. Second paragraph. "A literature search on oxycodone and oxymorphone is being conducted by one of the summer employees."

Do you know who was doing the literature search initially?

A. No. It would have been a son or daughter of one of the people who worked for Purdue Frederick or Purdue Pharma.

Q. Fifth paragraph down, second sentence says, "The current consideration is to develop 20, 40, 80 and 160 milligram tablets in addition to the 10 milligram tablets now in the clinic."

And whose idea was it to develop 20, 40, 80 and 160 milligram tablets?

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MR. STRAUBER: I'm sorry. Which page are you reading from, Mr. Thompson?

MR. THOMPSON: The first page, just what I called out, fourth paragraph, second sentence.

MR. STRAUBER: Okay. Thank you.

A. This was a team decision. It was discussed extensively.

Q. Then if you'll go to the second page, first paragraph, it says, "With regard to the package insert and the first year advertising claims, it was discussed that Mr. Segar should meet with others and rework the 'draft' package insert. The purpose would be to idealize the insert and coordinate the contents with the advertising claims and clinical trials program. The package insert should include comparative claims. It must be kept in mind this is a working document."

Why did you want to coordinate the package insert with your advertising claims?

A. The package insert is the Bible for the product. It is the core document from which all promotion or communication with physicians is to be based. It is typical in the industry that a lot of work is expended to make the package insert as comprehensive and complete as possible.

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Q. Then this is a -- you talked about physicians being aware of OxyContin being twice as strong as morphine a second ago. Let me hand you -- let's mark this as Exhibit 11.

(DEPOSITION EXHIBIT NO. 11 MARKED)

(Passing document.)

Q. This is an e-mail. It says the author is Dr. --

MR. STRAUBER: May I have a copy?

MR. THOMPSON: Right in front of you.

MR. STRAUBER: I'm sorry.

Q. It says the author is Dr. Richard Sackler at Norwalk dated 5-28-97.

Are you familiar with this e-mail to Michael Friedman?

A. Yes.

Q. Who is Michael Friedman?

A. He was head of marketing and sales.

Q. Okay. And let's drop down and see what Michael Friedman has written.

The first paragraph he says, "My purpose in writing this memorandum is to clarify our position on the very complex issues raised by Mike Cullen during the Phase IV team meeting and which were the subject of Dr. Richard's inquiry."

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When they say "Dr. Richards," who's that?

A. That was me.

Q. All right.

First paragraph. "We are well aware of the view held by many physicians that oxycodone is weaker than morphine. We all know that this is the result of their association of oxycodone with less serious pain syndromes. This association arises from their extensive experience with and use of oxycodone combinations to treat pain arising from a diverse set of causes, some serious, but most less serious. This 'personality' of oxycodone is an integral part of the 'personality'" -- "this 'personality' of oxycodone is an integral part of the 'personality' of OxyContin.

"When we launched OxyContin, we intentionally avoided a promotional theme that would link OxyContin to cancer pain. We specifically linked OxyContin to the oxycodone combinations with our 'old way, new way' campaign. We made sure our initial detail piece provided reps with the opportunity to sell the product for a number of different pain states. With all of this, we were still concerned that the drug would be slotted for cancer pain and we would encounter resistance in the non-malignant pain

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market."

And it says, "Our pricing of the product was geared toward the non-malignant market. We knew if we priced low per milligram for the higher dosed cancer patient we would be priced way too low per milligram for the standard non-malignant pain patient, where we really wanted to make a market. We feared that the 'cancer pain experts' would object to the two-to-one ratio" -- and that two-to-one ratio is the ratio of oxycodone -- OxyContin to morphine; is that correct?

A. Actually, if you want to strictly understand the ratio, the two-to-one would refer to the ratio of morphine to oxycodone.

Q. Okay.

A. Not the other way around.

Q. All right.

A. That's what you -- I know that's what you meant to say.

Q. Yes. Yes.

-- "and resulting cost of therapy for high-dose patients. However, we had no choice given our position for OxyContin. In any case, we're developing hydromorphone codeine" --

A. I've lost you here. "In any case" --

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what paragraph are you in now?

Q. -- "for the high-dose patient."

A. Okay. I'm at the end of paragraph 4.

Q. And then it says, "Despite our initial uncertainty, we've been successful beyond our expectations in the non-malignant pain market."

A. Yes.

Q. And non-malignant pain market is sort of the chronic arthritis, back pain, those types of patients?

A. Well, those are most typically moderate pain patients, some of them may be severe. But there are many less common conditions that produce severe, crippling, life-destroying pain. And we had an indication, and still have, for all pain states that are appropriately treatable with opioids for an extended period of time.

We wanted -- so non-malignant really is a distinction. All pain other than the pain directly caused by the encroachment and destruction of tumor tissue in the patient.

Q. And then he says here, "Doctors use the drug in non-malignant pain because it is effective and the personality of OxyContin is less threatening to them and their patients than that of the morphine

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alternatives. I apologize for this unspecific term, but I feel it captures the notion that there are image-related attributes that influence drug acceptance. While we might wish to see more of this product sold for cancer pain, it would be extremely dangerous at this early stage in the life of the product to tamper with this 'personality' to make physicians think the drug is stronger or equal to morphine. We are better off expanding use of OxyContin in the non-malignant pain states and waiting for hydromorphone, in 1999, to relaunch into cancer pain."

Why was it felt that there would be a danger -- it would be extremely dangerous at the early stage in the life of this product to tamper with this "personality" to make physicians think the drug is stronger or equal to morphine?

A. The context of this was, as you know, a thread of e-mails that actually, he alludes to, I started.

The whole context and the whole discussion of Mr. Friedman here and in other -- I'll pause here.

Q. No, go ahead.

A. Because I think it's really important

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for you to understand this.

The whole context was not to -- the context was not to stigmatize oxycodone in a way that morphine was stigmatized. Morphine was seen as an end-of-life extreme duress -- patient in extreme duress, often dying of cancer, but not only cancer. It was reserved by most physicians, if it was used at all, even when patients were in serious severe or even crippling pain, because telling a patient "I'm going to put you on morphine," "I'm going to prescribe morphine for you," "Now we've got to use morphine," however the physician told the patient, it often was associated with a death sentence. Oh, thinks the patient, he's telling me I'm going to die. Even worse, my doctor's putting me on morphine, he's giving up on me.

We didn't want oxycodone to -- to change the, as he says, personality of oxycodone, but you could say all the associated feelings of oxycodone, which were generally appropriate to a narcotic. We didn't want that to be polluted by all of the bad associations that patients and healthcare givers had with morphine.

Q. Did you think that if physicians thought it was stronger or equal to morphine, much

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less twice as strong as morphine, that they would be less likely to write prescriptions and sales of OxyContin would go down?

A. No. If its personality was changed, if it was stigmatized as an end-of-life drug, it could limit its usefulness. The term "stronger" here meant more threatening, more frightening. There is no way that this intended or had the effect of causing physicians to overlook the fact that it was twice as potent.

It was called out in virtually every promotional piece of literature, it was reflected in a conversion chart which we had developed for the few patients who were being treated with morphine where we made it very clear if they're on any dose -- daily dose of morphine, you cut that dose in half for OxyContin.

And every action we took before the product was launched with the FDA in the package insert and promotion and in all detailing emphasized that it was twice as strong. Some physicians had formed their own impression that it wasn't twice as strong, it was less strong, and we insisted that they observe -- we said, "With this drug, Doctor, it is twice as strong." Even when they said, "No, I think

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it's one and a half times as strong." And some physicians even said, "I think it's about the same potency as morphine." We would insist, "No. Please use it the way we have researched it and the way the FDA has approved it."

Q. Okay. Now --

A. And I think we were effective in getting that message across in time to most and eventually almost all physicians.

Q. Okay. This is 1997, two years after the launch of OxyContin Controlled-Release, correct?

A. Yes.

Q. So it's been on the market now over -- well, you launched it January '96. We're now in May of '97. And it says, "We are well aware of the view held by many physicians that oxycodone is weaker than morphine."

And the conclusion of this was, "I do not plan to do anything about that."

And you wrote back and said, "I agree with you. Is there a general agreement, or are there some holdouts?"

Is that what you wrote at the top of the e-mail?

A. I did. And I agreed with him then and

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I agree with him now because I knew what he meant, and so did everybody else know -- knew what he meant. And, more important, our actions in promoting the "twice as potent as morphine" never wavered. We never disguised it or hid it; we emphasized it.

Q. So you weren't doing this because the pain market for non-malignant pain was a much greater market share; is that your testimony?

A. No. No, that isn't. We wanted to address both markets. The e-mail -- which perhaps you want to explore or not. What started this was, as he says in the first paragraph, something that I had inquired about. And what I had inquired about was an error on my part.

When we -- before we launched OxyContin, we thought that our sales would be about equally divided between cancer pain and non-malignant pain. We knew that the market for non-malignant pain was much larger, of course. Fortunately for all of us, cancer is not -- is much less common than other pain states. But we had expected it would be about 50/50.

I had seen some report or had attended a meeting where I learned it was about 20 percent of our sales, and, thus, I wrote to Michael and said,

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why -- what's going on here? Why aren't we getting more cancer sales?

Q. Let's -- let's look at the e-mail you wrote to Michael Cullen at Norwalk. Let's mark this Plaintiff's Exhibit 12.

(DEPOSITION EXHIBIT NO. 12 MARKED)

Q. And Michael Cullen writes on June 2nd of '97 -- that was after the e-mail we were just looking at -- and says, "In recent team meetings we've discussed the issue that OxyContin is perceived by some physicians, particularly oncologists, as not being as strong as MS Contin."

Now, oncologists are cancer --

A. Yes.

Q. -- doctors, correct?

So even the cancer doctors don't think that OxyContin is as strong as MS Contin according to this, correct?

MR. STRAUBER: Objection to the form. That's not what it says.

MR. THOMPSON: Well, let me rephrase it.

Q. You were aware -- or at least Michael Cullen was advising you that OxyContin is perceived by some physicians, particularly oncologists, as not being as strong as MS Contin; is that correct?

A. That's what the words say.

Q. And he says, "Although this perception has had some effect with physicians switching to MS Contin with more severe cancer pain patients, it has actually had a positive effect with physicians' use in non-cancer pain."

And there he's saying non-cancer physicians that don't think it's as strong as MS Contin were having a positive effect from that.

And I assume it's talking about sales, wouldn't you?

A. Yes.

Q. He says, "Since oxycodone is perceived as being a weaker opioid than morphine, it has resulted in OxyContin being used much earlier for non-cancer pain. Physicians are positioning this product where Percocet, hydrocodone and Tylenol with codeine have been traditionally used."

So he's saying here physicians are using it because they think it's weaker than morphine, correct?

A. He's using the word "weaker," but not meaning less potent than morphine. Within this time it appears that people had fallen into a habit of

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signifying less frightening, less threatening, more patient acceptable as under the rubric of weaker or more frightening, more -- less acceptable and less desirable under the rubric or word "stronger." But we knew that the word "weaker" did not mean less potent. We knew that the word "stronger" did not mean more potent. And we knew that because, by this time surely, anybody who was using this product recognized it was more potent, they knew it was more potent.

So it's very unfortunate for your understanding as well as anybody else's understanding that all those issues of the stigma of morphine, of the frightening nature of morphine, of morphine being a cancer drug, end-of-life drug, it's very unfortunate for your understanding and for most people's understanding that the word "weaker" and "stronger" was used, but we understood what it meant.

Q. We're not done reading it yet, but let me ask you this.

A. Okay.

Q. You were advised by your senior employees that physicians perceived OxyContin Controlled-Release as less strong than morphine? Many physicians perceived it that way, correct?

A. Words used, but didn't mean that they

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believed it was less potent, because I knew they believed it was more potent. Their own practice proved they recognized it was more potent. As I said before, Percocet was 5 milligrams.

Q. Did you do any studies yourself or conduct any investigation to determine what percentage of physicians believed that OxyContin Controlled-Release was less powerful than morphine and were not aware it was twice as strong as morphine?

A. You're talking about less potent?

Q. Yes.

A. I don't know of such studies. But in common parlance in discussions with physicians, if really a substantial -- if any substantial number of them believed -- believed in the -- believed -- had an erroneous belief -- excuse me. If any had an erroneous belief and said to a representative, "Oh, this is -- this stuff is less potent than morphine," the salesman had ample materials to demonstrate to the physician that he was in error and was instructed to use those and did use it.

And I wish we had a survey -- had done a survey to demonstrate it in retrospect, but it was so generally accepted that it was at least one and a half times more potent by even the skeptics -- most

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skeptics -- and there weren't many -- but generally recommended to be twice as potent as morphine, it just never occurred to us.

Q. Sure. And it's your belief that your sales force was telling these physicians that it's actually twice as strong as morphine and correcting that misperception that they had?

A. Absolutely. It was in the package insert, the promotion, in the conversion tables, and in the recommended dosing, which --

Q. So promotional pieces, your symposiums, your review articles, your studies would all point that out?

A. I can't say that every one would point it out in every page, but it should have been an important part of most promotional materials.

Q. Let's read the rest of Michael Cullen's e-mail dated 6-2-97, well after the launch of OxyContin.

Paragraph 3 says, "Since the non-cancer pain market is much greater than the cancer pain market, it is important that we allow this product to be positioned where it currently is in the physician's mind. If we stress the 'power of OxyContin' versus morphine, it may help us in the

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smaller cancer pain market but hurt us in the larger -- larger potential non-cancer pain market. Some physicians may start positioning this product where morphine is used and wait until the pain is severe before using it.

"Marketing has decided that" -- and by that, they're talking about the marketing group, correct?

A. The marketing department, yes.

Q. Yeah, marketing department.

So it says, "Marketing has decided that the effects of the Phase IV team should be predominantly focussed on expanding OxyContin use for non-cancer pain."

And then if you look at the last paragraph, it says, "It is important that we be careful not to change the perception of physicians toward oxycodone when developing promotional pieces, symposia, review articles, studies, et cetera."

And what they're talking about there is, let's not clear up this misconception that physicians have that OxyContin is not as strong as NS Contin, correct?

MR. STRAUBER: I object to the form of the question, Mr. Thompson. You, in reading this,

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skipped over two sentences. I'd ask that you go back and read this with the two sentences that you omitted. The one beginning with "The sales force can teach the oncologists..."

MR. THOMPSON: Oh, sure.

Q. "Our approach to cancer pain will be to get physicians to use it earlier instead of products such as Percocet, Vicodin or Tylenol 3. The sales force can teach the oncologists the proper dose and titrate OxyContin to ensure that they stay with it as the pain increases."

Now, oncologists are the cancer pain doctors, correct?

A. Yes.

Q. That doesn't say anything about all the non-malignant doctors -- all the doctors that treat non-malignant pain, correct?

A. But they would be taught the same thing, how to titrate. Because that was the -- that was, in a sense, the fundamental doctrine of treating pain with opioids; start low and titrate.

Q. And -- well, the whole --

A. Adjust the dose, in other words, upward.

Q. Well, the whole purpose of this e-mail

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is that you not teach the non-malignant pain physicians that OxyContin is twice as strong as morphine and let them continue with their perception that it's not, correct?

A. No, not correct.

Q. Well, let's -- let's continue reading the rest of it, then.

The last paragraph. "It is important that we be careful not to change the perception of physicians toward oxycodone when developing promotional pieces, symposia, review articles, studies, et cetera."

Now, am I correct that what he's saying in here is, let's not clear up the misperception in any of our promotional pieces, symposia, review articles or studies?

A. Don't change the personality. Don't change this to an end-of-life cancer drug to a drug that shouldn't be used except at the end of life when everything else has been exhausted. That was the thrust.

I may just add something here. There's a conflation within this which you wouldn't understand, and that was in the first paragraph which you read where he said that oncologists think it isn't

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as strong as MS Contin. Here the meaning that we understood -- certainly I understood and anybody who was involved -- was the cancer doctors who were using the drug were stopping at -- they had established a notional idea based on their past habit of using Percocet that they shouldn't go above 40 to 60 milligrams a day of oxycodone. And the reason they developed that habit, that practice limit, was not because of the oxycodone, it was because of the Tylenol, which was the more toxic agent in that combination.

You're probably aware that recently the FDA has recommended lowering the maximum daily Tylenol dose from 4 grams a day to 3. But even then 4 grams a day was recognized as being the then practical limit.

So oncologists who were using oxycodone as Percocet were just in the habit, well, you're getting 40 milligrams a day of Oxycodone, your pain is coming back. Rather than titrate those patients to a higher OxyContin level, they said, Well, we've got to switch to something else.

And that was really what was going on and in part why oncologists' use of a product had not developed as well as we had wished that it would

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develop. And that was understood and contained within this dialogue, not all of it documented here.

Q. Yeah. Sure. Let's go back and talk about it a little bit more, then.

In the first paragraph he says, "We've discussed the issue that OxyContin is perceived by some physicians, particularly oncologists, as not being as strong as MS Contin. Although this perception has had some effect with physicians switching to MS Contin with the more severe cancer pain, it has actually had a positive effect with physicians' use in non-cancer pain."

So what he's saying there, if I'm reading this correctly, is that because they think it is not as strong as MS Contin, when they need a strong drug for cancer pain patients, some of the physicians aren't switching to it because they don't think it's as strong, and that may hurt sales a little bit there. But with the non-cancer pain, where you don't want as strong a drug as an end-of-life malignant cancer pain patient might need, it's actually helping our sales that they have this misperception because they are going ahead and prescribing it because they don't think it's as strong as MS Contin.

Is that what that first paragraph is

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saying?

A. You're -- that's what the words say. But the meaning of "strong" here would be effective. It is not as effective. And the reason they thought it was not as effective is, they had a mental notion of a limit and they didn't follow the doctrine of titrating -- increasing the dose when the pain is getting worse.

And all of this was greatly known. I mean, by 1997 most of the people who disagreed and thought that OxyContin was not two-to-one, they thought it was one-and-a-half-to-one, that was by far the most common objection. Still stronger than morphine, but not quite as much stronger as we said it was. They had been persuaded if they used the drug, oh, yes, particularly those oncologists who switched from MS Contin to OxyContin.

Q. So then he says, "Since oxycodone is perceived as being a weaker opioid than morphine, it has resulted in OxyContin being used much earlier for non-cancer pain." Correct?

So he's saying more people are using it earlier for non-cancer pain because they think it's weaker?

A. Not -- not less potent. More

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acceptable to the patient, not frightening, not stigmatized as morphine unfairly was by history. That was the meaning.

And I've lost my thought here. Could you just repeat your question so I can finish my answer?

Q. Sure. And what he's saying here is, the non-cancer pain doctors -- which is the much bigger market share when you're trying to sell OxyContin, is the non-malignant pain market -- it's actually helping sales there because they don't think it's as strong as morphine?

A. Again, as I've testified before, the term "stronger" and "weaker" was a very unfortunate term.

Q. Do you want to use "effective"?

A. In the case of here, "effective," yes, in the case of cancer. Because they were using it.

Let me explain one other thing. At the time that this product was introduced, the World Health Organization had promulgated a stepladder approach to cancer pain. And when OxyContin was introduced, we properly, with the agreement of the FDA, said that MS -- that OxyContin was appropriate for the second step and the third step. That's where

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the start with and stay with theme came from.

So I know that this could cause real confusion reading these documents if you're not involved day to day, but there is no way that any of the people on these documents understood "stronger" to mean more potent, "weaker" to mean less potent. We had never departed from a strong promotional theme, that it was twice as strong as morphine.

Q. And then down at the bottom he says -- or let's take the middle paragraph. "Since the non-cancer pain market is much greater than the cancer pain market, it is important we allow this product to be positioned where it currently is in the physicians' mind."

And that means let them believe that OxyContin Controlled-Release is not as effective as morphine?

A. No. I said the effectiveness really applied to the oncologists who were saying, This isn't as effective, or, you know, I have to -- when the pain gets really bad, I switch them to something else. And that was the one place or the one circumstance in which we understood it as effective. And I've explained that we believe that that was a consequence of them just having a mental limit.

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Q. Sure. He says, "If we stress the 'power of OxyContin' versus morphine, it may help us in the smaller cancer pain market..."

That means let them know that it is more powerful than morphine; that will help in the smaller cancer pain market, correct?

A. That's what he says.

Q. Yeah. "...but hurt us in the larger potential non-cancer pain market. Some physicians -- physicians may start positioning this product where morphine is used and wait until pain is severe before using it."

A. He's coming back probably to the cancer market. I'm not sure. But we always said it was a powerful drug. We implied that. We didn't use the words. Because words can elicit a whole variety of responses.

Q. And then, "The marketing department has decided that the efforts of the Phase IV team should be predominantly focused on expanding OxyContin use for non-cancer pain."

A. Right.

Q. That's the -- that's the group that if you clear up the misperception may be less likely to prescribe according to what he's written here,

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correct?

A. If you change the -- if you change the character of the drug in their mind. If you tell them it's a cancer drug, it's for end-of-life care, yes, you might change their perception. We didn't believe that that was appropriate, nor did the FDA, nor did the opinion leaders believe it was appropriate. It truly was a drug that, in appropriate doses, could manage moderate and severe and extremely severe pain where patients needed an opioid to manage their pain.

It's important, also, that you understand that for a hundred years, and even today, there is no drug that is more effective or safer than opioids for treating pain over a long term. And it was a shame that when -- that for decades no opioid was used in many -- most, perhaps overwhelming majority of patients who had severe pain.

Q. Do you think it might compromise patient care if Purdue Pharma allowed patients' physicians to believe that the drug they are prescribing them is weaker than morphine?

A. Could you just repeat the question?

Q. Yes.

A. I just want to get the question straight.

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Q. Do you think it might compromise patient care if Purdue Pharma was aware that many physicians felt like OxyContin was weaker than morphine and did nothing to clear up that misconception?

A. No. If they believed it was less potent than morphine, we clearly cleared up that misconception. We told them it was twice as potent. We told them to use doses that were considerably lower than the morphine doses that they might have been accustomed to. What we didn't want to do is to turn this into a cancer drug.

Q. Right. And this is 1997.

A. That's correct.

Q. Well after the launch, well after your package insert has been put out and all that, correct?

A. Yes.

Q. And Michael Cullen says, "It is important that we be careful not to change the perception of physicians toward oxycodone when developing promotional pieces, symposia, review articles, studies, et cetera," correct? Is that what he wrote?

A. It looks like that's what he wrote.

Q. And you replied to him and did not say, no, we need to clear up this misconception immediately. What you said is, "I think that you have this issue well in hand."

A. That's correct.

Q. "If there are developments, please let me know."

A. That's what I said. But the misconception that you're referring to didn't exist. The misconception that this was a benign, harmless, weak drug for treating pain was not the perception that existed. So that was not the error that he -- I don't know quite what he -- let me just read what he said here.

What are we reading from, please? We've gone through this a number of times, so where were you reading from here?

Q. We were reading from --

A. You just read me something from --

Q. From your top where you said "I think that you have this issue well in hand."

A. But where you said I was responding, where was that?

Q. Where he says, "It is important that we be careful not to change the perception of physicians toward oxycodone when developing promotional pieces, symposia, review articles or studies."

A. That's correct. Not change the character of the drug, not change -- not change it into a frightening, scary, end-of-life drug.

Q. All right. Let me hand you -- let's mark this as Plaintiff's Exhibit 13.

(DEPOSITION EXHIBIT NO. 13 MARKED)

(Passing document.)

Q. This is an interoffice memo dated 1994.

MR. STRAUBER: You gave me two copies.

Q. And this is from Michael Friedman. What was his role in 1994?

A. He was head of marketing and sales.

Q. And it's to?

A. To the three people he reported to.

Q. And that's Mortimer Sackler, Raymond Sackler, and Dr. Richard Sackler, which would be you?

A. That's correct. Yes.

Q. And under "Discussion," if you go to page 4, it says, "We believe that the FDA will restrict our initial launch of OxyContin to the cancer pain market."

Did you believe that at the time?

A. He may have believed it; I didn't believe it.

Q. Okay. "However, we also believe that physicians will perceive OxyContin" --

A. Where are you reading from, which number?

Q. Next sentence, 1.3.

A. 1.3. Thank you.

Q. "However, we also believe that physicians will perceive OxyContin as controlled-release Percocet without acetaminophen and expand its use."

Now, is OxyContin Controlled-Release Percocet?

A. Without acetaminophen that would be one way of describing it, because there are only two active ingredients, acetaminophen and oxycodone.

Q. Is -- is OxyContin Controlled-Release more powerful than Percocet?

A. It depends on the dose. The initial dose at 10 milligrams twice a day would be equivalent to the standard introductory dose of Percocet four tablets -- one tablet four times a day; in other words, four. So it would be the same dose.

Q. When you-all did studies, did you find

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out that 10 milligrams of OxyContin had the same effect as a placebo and it was really only the 20 milligram that was effective?

A. I don't recall that, but it's possible.

Q. "We do not want to position OxyContin in a way that will discourage physicians from using OxyContin for the chronic non-malignant pain, especially" --

A. Where are you reading from again?

Q. Next paragraph.

A. Okay.

Q. I mean next sentence.

-- "especially when we have studies available that demonstrate efficacy and safety for this indication."

A. Okay.

Q. Do you know what your studies showed about non-malignant chronic pain patients developing tolerance or dependency or withdrawal from OxyContin?

A. I don't have them immediately in my mind.

MR. THOMPSON: Let's mark -- that's been marked, correct?

MR. DANFORD: Just off the record.

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VIDEOGRAPHER: We are off the record at 11:45 a.m.

(RECESS)

VIDEOGRAPHER: We are back on the record at 11:57 a.m.

BY MR. THOMPSON:

Q. I'm going to hand you a document that is dated April 23, 1997.

(Passing document.)

And on the bottom of page 1 is an e-mail you sent regarding San Antonio, and it says -- it's 4-22-97. This is PDD1701801141. And it's to, it looks like, Michael Friedman.

"Michael, I am somewhat surprised that 18 months into marketing significant groups of experts, oncologists, for example, believe that OxyContin has a ceiling effect."

What did you mean by "ceiling effect"?

A. Has a dose above which it would not be effective. That was what I meant, not be effective.

Q. Okay. "What materials could we pull together that would smash this critical misconception? Can we put together some approaches and test whether they would be potent weapons in this effort?"

And he writes back and says to you,

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"There will always be misconceptions about drug substances. For controlled-release drugs, many of these misconceptions are the result of residual attitudes associated with the immediate-release forms."

I'll just read the whole thing.

"For example, morphine has a 'personality' that was shaped when it was an IV drug. Oxycodone has a 'personality' that was influenced by many years of Oxycodone use in Percocet. We built a large part of our platform on this personality and it is to differentiate OxyContin from MS Contin and Duragesic. This differentiation has led to much non-malignant business.

"Marketing" -- this is the next paragraph.

"Marketing is not only about what you are, but it's about what you are not. We have had success beyond our expectations that is in part due to the unique personality of OxyContin. Even as we seek to increase the use of the drug in higher doses, we should be very careful. As you know, the strength of the drug is principally a barrier in malignant pain. If we do not want to change the image in a way" -- I'm sorry. "We do not want to change the image in a way

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that will discourage non-malignant use. A barrage would be ill advised."

And you wrote back, "Excellent points. What about rifle shots?"

Is that correct?

A. That's correct, that's what I wrote.

Q. And over here before that, there's a letter to you from James Lang, and he's pointing out that he sat in some oncology focus groups and --

A. What page is that?

Q. It's page 2.

A. The second page of what you handed me? Oh, Jim. Yes. Okay.

Q. It says, "Issues affecting the oncologists' utilization of OxyContin are: M.D.s feel the product dosing has a ceiling; don't feel it is as strong as MS Contin; like and are very comfortable with MS Contin and don't see a need for another product except where MS Contin fails.

"Interestingly, when asked to describe what they like about OxyContin, they for the most part cited all the key points our reps are or should be stating in their sales presentation.

"The anesthesiology focus group Saturday evening was of less value however. Their

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primary concerns were the Medtronic pump being used by the orthopods and the need for Purdue to educate surgeons on proper post surgery pain management and fears with opioid prescribing."

Is that the e-mail that prompted you to write the letter?

A. It might be; I don't recall.

Q. I'm sorry, prompted you to write your e-mail.

A. It could be.

MR. THOMPSON: Why don't we mark that as Exhibit 14.

(DEPOSITION EXHIBIT NO. 14 MARKED)

A. But I'm not sure. It could have been there could be another e-mail in which I pointed out the lack of sales development with oncologists as compared to our plan. So I'm not sure that this is -- but it would have been around the same time perhaps. Maybe I looked at the results with oncologists after I read this.

MR. ELLIS: That's already in evidence. It's either Exhibit 2 or 3. It's the May 1993 memorandum. Here we go.

MR. THOMPSON: All right.

A. Are we finished with this

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(indicating)?

Q. Yes, sir.

I wanted to go back to the May 1993 memorandum.

(Passing document.)

And this is the --

A. July '92?

MR. STRAUBER: What exhibit number are we talking about?

Q. Wait a minute. Let me -- can I see what you have here?

(Passing document.)

Let me just clear this up. It's not in evidence yet. April 2nd, 1993.

Let's -- I'm sorry. I misspoke.

Let's -- let's jump to the April 2nd, 1993 memorandum.

Let's mark this as Sackler 15.

(DEPOSITION EXHIBIT NO. 15 MARKED)

(Passing document.)

Q. What is "PFRC" at the top of this?

A. Purdue Frederick Research Center.

Q. And it's the R&D meeting?

A. R&D meeting.

Q. And it is dated April 2nd, 1993, correct?

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A. That's what it says.

Q. And the part I wanted to ask you about, if you go back to page 10 -- and you were in attendance at this meeting, correct?

A. I don't -- let me check that. I certainly don't recollect by date.

Q. R.S. Sackler attended.

A. Yes, that was me.

Q. All right. So on page 10, it looks like you're discussing an osteoarthritis study that was being done.

A. Okay. Where on page 10?

Q. I am on the third paragraph.

A. Okay. I'm sorry.

Q. Fourth paragraph.

A. It says page 10, but it doesn't look like what you have here.

Q. That's it.

A. Is it?

Q. Yeah.

A. Okay. Pardon my eyesight.

Q. So read along with me the section over here "RR." Do you know who "RR" is?

A. Robert Reder.

Q. What was his job at that time?

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A. He was senior medical researcher.

Q. And he says here in this paragraph, "The protocol for the placebo-controlled study versus two dose levels in patients with osteoarthritis was discussed with C. Wright."

Would that be Curtis Wright?

A. That's -- that's what I would understand it to be.

Q. And at that time he was the person who was reviewing your-all's OxyContin submission to the FDA?

A. He was the medical reviewer, that's correct.

Q. And he's the guy that actually approved it to be sold, you know, allowed you-all to sell it from the FDA?

A. That's my recollection.

Q. You-all ultimately hired him a few years later, didn't you?

A. We did hire him, but not after his tenure at the FDA. We -- he spoke to somebody at Purdue when he was planning on leaving the FDA, and Paul and I discussed it and agreed that we should not hire somebody who had -- who had reviewed our product and had left. And so he went to another company,

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regrettably for us, because he was very, very knowledgeable --

Q. Sure. He went there --

A. -- and very smart.

Q. He went there for a short period of time and then came to work for you-all?

A. I don't remember. It was certainly -- it was certainly -- my recollection is a couple of years, two or three years, but I don't recall exactly. The record, I'm certain, could be produced.

Q. All right. Well, let's -- let's take a look at page 10. "The protocol for the placebo-control study versus two dose levels in patients with osteoarthritis was discussed with C. Wright. He stated there were very strong opinions of members at the FDA that opiates should not be used for non-malignant pain. And this study" --

A. Let me just follow you, if I may. I'm a slow reader, I'm sorry, but I just do want to follow you.

Q. Great. Well, I'll read it again.

A. Okay.

Q. "He stated there were very strong opinions of members at the FDA that opiates should not be used for non-malignant pain and this study would

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not be greatly accepted by the FDA as it is written now for that reason. C. Wright has suggested rewriting the protocol in order to make it clear osteoarthritis is being used as a convenient pain model. He would also like the open label extension to be eliminated from the protocol."

Now, what do you refer to as the open label extension?

A. In many trials of chronic-use drugs, after the trial period, which might have been 12 weeks, was completed, the subjects in the trial were given an option to continue being treated and monitored by their physician. It's completely at their election or choice. They -- they -- some decide that they want to, some decide that they don't. And we continue them on medication for an extended period of time. This is extremely common in all kinds of trials.

Q. "P. Goldenheim stated the open label extension could be done as a post-marketing study. B. Kaiko and R. Reder will meet with P. Lacouture to communicate what is necessary to revise the protocol. The protocol must be clear that we are not going for a general indication for the treatment of osteoarthritis with osteo -- with oxycodone."

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And then down below that it says, "Dr. Richard Sackler asked if there was consensus within the pain group about the appropriate use of opiates for certain patient groups. B. Kaiko stated this is very -- a very controversial area, and most people in the pain group say that well-controlled studies are necessary to investigate the questions."

"Dr. Sackler" -- next paragraph says, "Dr. Sackler has suggested a smaller group meet in-house to clarify the political issues."

What were the political issues?

A. The political issues would have referred to the preferences and the sometimes prejudices of physicians and other experts.

Q. Over whether you should prescribe opioids for non-malignant pain at all?

A. And for what conditions in non-malignant pain. I don't think there were very many people, or any people really, of any reputation who would have proscribed, that is prohibited, the use of opioids for non-malignant pain, but there were a lot of opinions when it came to listing one condition or another or another or another.

Pain is the most common symptom that patients have and present to doctors, and so every

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doctor has his own opinion as to what is -- what is best and what is appropriate for treating pain, or in some cases what pains are not appropriate to be treated at all. And this is a highly -- is a highly personal and contentious issue in the medical world and has been so for a hundred years.

Q. And that's the reason that morphine was stigmatized and not prescribed generally for non-malignant pain, it was more reserved by physicians for end-of-life Hospice care and cancer pain in the medical community?

A. I don't understand the connection you're drawing. I think the situation with morphine is unique and it doesn't relate to what we're talking about here.

Q. What about heroin, was it prescribed for --

A. For pain?

Q. -- pain?

A. It is prescribed for pain in many countries and is part of the pharmaco -- the pharmacopeia. For example, it is very popular in the UK.

Q. Is it controlled?

A. It is, just like morphine.

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Q. Is it used for end-of-life pain mostly?

A. I can't tell you that because I don't know. But it is -- it's -- I don't believe that it established itself as an analgesic in the United States at any time even when it was -- was an analgesic and was available.

Q. I'm going to hand you a memo --

A. Are we finished with this (indicating)?

Q. Yes, we are.

I'm going to hand you a memo dated -- Project Team Meeting Minutes of Tuesday, August 17, 1993.

(DEPOSITION EXHIBIT NO. 16 MARKED)

(Passing document.)

Q. It says here under "Marketing," "There's some initial interest in having a 5 milligram and 10 milligram immediate release Oxycodone capsule produced."

Do you know why marketing wanted those produced?

A. I -- I could -- I could guess, but I don't know specifically why they wanted it.

Q. Well, if you don't mind, turn back to page 4. And on page 4 what I really want to ask you about is potential studies.

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A. Okay.

Q. And Mike Innaurato is the guy we mentioned earlier who was in --

A. Innaurato, yes.

Q. -- in the marketing department, correct?

A. Yes. Yes.

Q. And he's the guy in charge of perhaps the sales force that goes out and tries to sell?

A. No. He would be in charge of the marketing execution of the strategy. So he would be intimately involved with the promotional materials, secondarily involved with training, and would be the person who would set the direction and themes that would be used. But he wouldn't be a person who would be responsible for sales, although he might go out in the field, and he should, to determine what is happening.

Q. Let me rephrase it then.

A. Sure.

Q. As part of marketing, he's the guy who is supposed to get the word out and hopefully increase sales by advertising the product and convincing people to write prescriptions?

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A. Not directly. The salespeople were the principal agents of getting the word out, to use your expression.

Q. All right.

A. Of putting the materials in the hands of doctors, et cetera. I don't recollect that advertising ever played much of a role in the promotion of OxyContin.

Q. Let's talk about -- if you'll look at 4.3, "Potential Studies." "Mike" -- I'm going to read that paragraph. "Mike Innaurato said that an OxyContin versus Percocet comparative study" --

A. Oh, you weren't reading -- I see.

Q. From "Potential Studies."

A. Okay. I'm sorry, this is so small, it's not too easy.

Q. "Mike Innaurato" -- and, unfortunately, that's the way Purdue gave it to us, so we're stuck with it, too.

"Potential Studies: Mike Innaurato said that an OxyContin versus Percocet comparative study would be useful for marketing purposes."

Now, in trying to decide whether the drug is safe, is it normal to have the marketing people decide what studies will be done?

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A. They might be involved in commenting on it or suggesting things, but normally it's the medical department that has the primary responsibility both for the medical research strategy and the -- and certainly the implementation.

Q. "Through such a study" -- I'm going to read the next sentence. "Through such a study (OC88-1105) has previously been conducted and published in abstract form, it was a single-dose study using non-GMP released material. Mike Innaurato stated that a multiple-dose study would be best to support claims relating to relief of post-surgical pain, low back pain and herpetic neuralgia pain."

From my review of that, it looks like he's got claims he wants to make and is trying to design studies to support them.

Is that what that appears to you?

A. No. He -- half yes, half no. What I think he is doing here in the general is he is, in a group meeting, presenting ideas for consideration by the group. Certainly this was not directed and he was not in a position to direct any studies be done or not done.

Q. Then the next sentence says, "Mike

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Innaurato stated marketing would like to position differently than MS Contin. Robert Reder" --

A. Just a second.

Q. Who is Robert Reder?

A. He was the senior medical officer in this -- in this minute of the meeting.

Let me just read -- catch up to you.

Q. "Robert Reder stated that the FDA has suggested that we do not issue claims supporting the general use of a Schedule II opiate in patients with non-malignant pain. Robert Reder indicated that decisions to make additional claims could be developed after the product is marketed. Jim Conover agreed with Robert Reder, but added that any study conducted in a patient with non-malignant pain could be included in the clinical studies section of a package insert.

"Robert Reder added that any proposed marketing claims and their supported studies should be first reviewed with our legal and regulatory departments; perhaps the marketing concepts could be reviewed now. Robert Reder stated that the marketing could start thinking of a five-year plan on potential marketing studies and strategies."

Did I read that correctly?

A. You did.

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Q. I'm going hand you -- let's mark this --

A. Are we finished with this?

Q. -- Exhibit 17.

(DEPOSITION EXHIBIT NO. 17 MARKED)

(Passing document.)

MR. THOMPSON: If I haven't done it, I'm going to move to admit all these into evidence as Exhibits 1 through 16 and 17.

Q. And this is a -- appears to be a speech you gave, is that what this is, or a publication you made?

A. This looks like it was a newspaper or magazine-like internal document for the field force principally. I think it was basically the field force. And -- and in-house marketing and salespeople would like to see their picture there or be quoted or whatever.

Q. And it's the winter of 1996; is that right?

A. That's correct.

Q. And if you'll turn to page 8 for me, please. I'm sorry, I misspoke. Turn to page 2, please. Over on the third column --

A. Yes.

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Q. -- halfway down it says, "The development and launching of OxyContin Tablets is the first time that we have chosen to obsolete our own product, and we have done it before the competition has slowed our growth of sales."

And you were referring to MS Contin that you obsoleted; is that correct?

A. That's correct.

Q. And then at the bottom it says, "We have the most powerful selling package insert in the category and in the industry."

And is that accurate?

A. I'm trying to see where it is. "We have" -- which paragraph in that column?"

Q. The very last paragraph.

A. Yes, that is correct.

Q. And if you'll turn to page 8. It says "Speech" at the top, "continued from page 2." So I'm assuming this is a speech you gave?

A. Maybe, but I don't know. We'll see.

Q. "OxyContin was brought to NDA" -- What's NDA?

A. "...to NDA filing." That's the filing of the new drug application.

Q. Right.

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-- "from early Phase I work on time and in an incredibly compressed period of two years' time."

That's because an NDA usually takes longer, correct?

A. Well --

Q. And let me just preface it with, the reason that it takes longer is because there's a number of studies that have to be done, both animal and human, to determine if a drug is safe and efficacious, correct?

A. Right. In general, that's correct.

Q. But in this case you-all got it done in an incredibly compressed period of time of two years.

"Robert Reder set the goal in November of '93 to file by December 31st, '95, and we submitted on December 28th, '95, three days ahead of schedule. This didn't 'just happen.' It was a deftly coordinated planned event that took dozens of workers years of effort to succeed."

A. True.

Q. "The most demanding NDA package for any analgesic product ever submitted didn't languish at the agency. Unlike the years that other filings

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linger at FDA, this product was approved in 11 months, 14 days. Our previous best approval time for other products was measured in years, not months.

"Much can be attributed to the unparalleled teamwork of the product team and the FDA's approval team which came into being as a result of our joint desires to operate within the context of a new time frame. Both we and the Pilot Drug Division of the FDA were motivated by the same goal to set the high standard NDA with the broadest indications approved in the shortest possible time frame."

Did I read that correctly?

A. You did. Did you have any questions about that?

Q. No. I just wanted to know if that was the statement you got and is it accurate?

A. This was a -- I believe it is accurate. I'm certain that the facts in there were accurate. The tone was very upbeat, almost a team enthusiasm building expression. I believe the facts are correct. And I perhaps -- I don't regret trying to energize our sales force, I think that was my mission. But this isn't what I would have written if a board had been -- or said if the board had been there. I wouldn't have been -- the tone would have

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been more restrained. I'm not embarrassed by the tone. In the context, I think it was very reasonable.

Do you have any questions about the reason it was so quick or anything else?

Q. No. We've got a lot of documents to get through, so I'm trying to hit the high points and ask you about those.

A. Okay.

Q. One of the things that they wrote you --

MR. THOMPSON: Do you have the other pages of this (indicating)?

MR. ELLIS: Yeah. Here. Right here.

(Passing document.)

Q. -- when you got your approval.

(Passing document.)

If you'll look at the last page on overall conclusion. And this is a document from the Medical Officer Review, Curtis Wright.

A. This is part of the approval -- part of the FDA approval process.

Q. He's the guy that now works for Purdue Pharma, correct?

A. No. No, he hasn't worked for Purdue Pharma for a long time, regrettably.

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Q. He was hired by Purdue Pharma subsequently, correct?

A. He was hired by Purdue Pharma --

Q. In his last --

A. -- maybe three years after this. I don't recall exactly.

Q. Why don't we go ahead and mark this as Exhibit 18.

(DEPOSITION EXHIBIT NO. 18 MARKED)

Q. His overall conclusion on the last page is, "CR Oxycodone" -- that's controlled-release, correct?

A. Yes.

Q. -- "appears to be a b.i.d. alternative to conventional q.i.d. Oxycodone. Approval is recommended. Care should be taken to limit competitive promotion."

What is "competitive promotion"?

A. I'm not sure what he meant. I could guess that he means promotion comparing this to other agents that are used in various pain conditions, but that's a guess on my part.

Q. And, then, I think the next sentence explains it. He says, "The product has been shown to be as good as current therapy, but has not been shown

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to have a significant advantage beyond reduction in frequency of dosing."

So other than you don't have to take it as much, the FDA has concluded that there's no benefit other than -- "it has not been shown to have a significant advantage beyond reduction in frequency of dosing"?

A. Not been shown in the NDA, yes.

Q. All right. Let's --

(Knock at the door.)

THE WITNESS: Probably announcing lunch.

MR. THOMPSON: Probably so. Let's go off the record.

VIDEOGRAPHER: We are off the record at 12:32 p.m.

(RECESS)

VIDEOGRAPHER: We are back on the record at 12:32 p.m.

(Passing document.)

Q. This is the OxyContin Project Team Memo.

Do you know if you ever reviewed this memo?

A. I wasn't on the project team. I don't

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know if I reviewed it. I'm curious. I could read through this. Was it sent to me or not?

Q. I don't know if it was or not.

A. It looks like I was not on the circulation list.

Q. Well, this list down here is -- yeah, there's a circulation list. It appears that it was not.

And, if you would, go over to page 4. The last paragraph down at the bottom, 6.2, "Mike Innaurato asked if marketing would be able to review the package insert."

Do you have any idea why marketing wanted to review the package insert?

A. Surely. They have many reasons.

Q. "Robert Reder stated the package insert will be circulated to marketing and other reviewers at the same time as the protocol review."

A. As I said earlier, the package insert was becoming -- originally, 20 years prior to this, package inserts were very, very brief and very simple. Over time the agency wanted them to be more complete documents, and then it had regulatory implications, as well.

So if you look at the history of use

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of package inserts, they, by this time, had become fairly long and extensive documentation for the physician. Their notion of being printed in that tiny format and stuck with every package in a sense was inconsistent, so you ended up sometimes having this package insert that was as big as the bottle adhered to every bottle. But it was available to physicians in a variety of other forms. The Physician's Desk Reference, I think you must be familiar with, which was the way most physicians then would read a package insert. It was just a compilation of all the approved products package inserts.

Q. What is marketing going to add to that?

A. First of all, they have to understand what the package insert is going to say about the product so that they can think of how they're going to present promotional materials.

Secondarily, they might, if the package insert is in draft form and under discussion with the agency, turn to the responsible medical officer as an example or the regulatory people and say, you know, this could be misunderstood, this could represent a problem, and so they would contribute to the clarity.

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But the medical department was, and regulatory department, were the principal owners of the document in the company. And the owner of the document for the government was the Food and Drug Administration, and, of course, they had determinative power as to what it -- what it ultimately ended up as.

Q. Sure. If you'll turn to page 5 under 7.0, "Marketing."

A. Yes.

Q. It says, "Post-Marketing Studies (QQL, Pharmacoeconomic, Percocet, Duragesic) - Robert Reder discussed some of the planned post-marketing studies. These included an OxyContin versus MS Contin comparative study, the Duragesic study, which is currently on hold, and a relative potency study comparing OxyContin to MS Contin.

"Robert Reder stated that we would need additional studies to recruit several hundred patients in order to get data to support claims for non-cancer pain."

This was in March of 1994. Do you know if those studies were done?

A. I'm sure they were done after approval, but I don't know whether any were done before approval.

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Q. Do you know if they were done before the drug was put on the market?

A. I don't know.

Q. Okay. Who is Robert Reder?

A. He was the senior medical officer on this project at Purdue Frederick.

Q. And then it says, "Mike Innaurato" -- again, he's the marketing guy, correct?

A. Right.

Q. -- "stated that a Percocet comparative study would be of benefit to marketing. Mike Innaurato replied to Bob Kaiko's question on claims by answering that equal efficacy of OxyContin to Percocet with better quality of life would be a beneficial claim. Mike Innaurato stated in the future Tramadol would pose a threat to the OxyContin market."

And then down below that it says, 7.2, "Marketing Claims/Studies Desired - Mike Innaurato gave a presentation on the results from the focus groups. A copy of the market research results would be issued to the OxyContin team. The results of the focus groups are attached. The results cover issues such as benefits, positioning and claims."

Do you know whether the studies recommended by Robert Reder were done before it went

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to market or the studies requested by the marketing guy were done before it went to market?

A. I don't know.

Q. Then there is a -- if you go to page -- the very last page, I guess, it is -- "OxyContin Presentation 3-22-94" up at the top.

A. Just a second. "OxyContin Presentation." I see it.

Q. And it says down at the bottom, it's got all the list of -- "OxyContin will be positioned as the only opioid combining the efficacy and safety of Oxycodone with the convenience of a 12-hour schedule, which allows for precise and accurate conversion and titration, while allowing the patient to lead a more normal quality of life. OxyContin is the opiate to start with for patients who may be on Percocet, Lortab or Vicodin and the opiate to stay with as the disease progresses."

Now, that was a marketing campaign, correct, the "Start With, Stay With"?

A. Yes.

Q. And the "Start With, Stay With" campaign, do you know who came up with the "Start With, Stay With" marketing campaign?

A. I wish I could lay claim to it, but,

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no, I don't know who came up with it.

Q. And then it says --

A. That was not the launch campaign in a sense. It may have been a subtext of the launch campaign, which was the old way and the new way. But...

Q. It says at the bottom, "Less potential abuse than other opioids."

Do you know where that claim came from?

A. I don't know. Looking at -- is this after the package insert? No. No, it's before the package insert was approved. I don't know.

Q. Do you know whether OxyContin had less potential abuse than other opioids?

A. I don't know what this refers to.

MR. THOMPSON: Let's mark that as 19 and move to admit it into evidence.

(DEPOSITION EXHIBIT NO. 19 MARKED)

Q. And here is this one.

(Passing document.)

This is PDD9520821306. This appears to be the --

A. Do you want to mark it?

Q. Yes, let's do that.

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(DEPOSITION EXHIBIT NO. 20 MARKED)

A. Now it's 20.

THE WITNESS: Are you keeping these?

MR. STRAUBER: Yes.

THE WITNESS: Okay. It's No. 20.

Q. "OxyContin Tablets Project Team."

A. Okay.

Q. And this is June 22nd, 1994, correct?

A. That's what it says.

Q. And on page 2, "Marketing" it says --

A. Wait, wait.

Q. -- 1.0.

A. I see June 8th, not June 22nd.

Q. Oh, the date it's sent is June 22nd over on the right.

A. Woops. Okay. My mistake. Okay.

Q. But it's project team meetings from June 8th, you're correct.

On page 2 under 1.0 "Marketing," under the "OxyContin Tablets Project Team Meeting Minutes," "Mike Innaurato gave an overview of the Oxycodone market referring to sales and growth charts and prescription data. Mr. Innaurato also presented our current strategy for introducing OxyContin Tablets to the market. OxyContin Tablets will be targeted at the

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cancer pain market."

Was a decision subsequently made not to target specifically at the cancer pain market?

A. I would infer that, but I don't know when.

Q. But at least by June 8th of '94 the plan was still to target the cancer pain market?

A. Yes. It doesn't say, however, that we -- let me just read this again. "Will be targeted at the cancer pain market."

It doesn't say that it will not be promoted to the non-malignant pain market.

Q. It says, "OxyContin Tablets will be targeted at the cancer pain market. Since it is possible that morphine generic products may soon be in competition with MS Contin Tablets, we will target patients who are currently receiving MS Contin as well as those patients thought to eventually use MS Contin Tablets (i.e., on the analgesic ladder late step one, step two and step three). The bulk of opiate business comes from 7,500 physicians, 3,000 of whom are oncologists."

A. That's correct.

Q. So you-all had market share from MS Contin, correct?

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A. Yes.
Q. And in order to keep from losing that market share to generics who are going to be priced much lower than MS Contin generally, correct?
A. That was the trend at that time, yes.
Q. What you did is put out OxyContin and obsoleted MS Contin, and if you could keep the MS Contin market through the use of OxyContin, you wouldn't lose any market share there; and if you could expand it to non-malignant pain, you would gain all of that market share, correct?
MR. STRAUBER: I object to the form of the question. At the minimum, it's compound.
MR. THOMPSON: Sure.
Q. Go ahead, you can answer.
A. So could you just break it into two questions and I'll answer them both?
MR. THOMPSON: Can you read the question back?
THE WITNESS: And stop after one.
(Record read.)
A. Okay. And that's what this seems to say, and certainly that was an element of consideration and part of the strategy. What I think might be missing here is any discussion of the

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non-malignant pain market, which you asked me a question.
THE WITNESS: Could you read question two?
(Record read.)
A. We would not -- we would not gain all of the non-malignant pain market share, but we could augment or add to the cancer pain market non-malignant pain.
And I'm quite surprised, actually, that this didn't discuss non-malignant pain as late as June 8th. So for whatever reason, the -- either Mr. Innaurato or the person who was writing the minutes didn't seem to include that, because I don't think -- not to my recollection was there ever consideration of restricting this product to malignant pain alone. It was widely used. Percodan, Percocet were widely used in non-malignant pain.
Q. Down below that it says, "Marketing has been interviewing potential advertising groups and is close to selecting one."
Do you know which advertising group was ultimately selected?
A. I don't know, but I'm sure we could find out if that were important.

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Q. And then under "Publications," right below that, "Manuscripts for studies C90-0708 and OC93-0101 have been sent to Drs. Stanski and Mandema for review as potential authors."
Why was Purdue sending out manuscripts to doctors to be potential authors?
A. I can't say for sure, but two possibilities arise in my mind. One possibility is that the manuscript had come to us in draft form and we had helped them fill in details, such as the references and so forth. That was one of the ways that companies helped authors lighten the burden, so to speak, of writing a paper.
The second possibility is the first draft might have been written in-house and sent to them for their review and their correction and additions.
Q. Well, it says "as potential authors" --
A. Yes.
Q. -- meaning it would appear that they authored the manuscript even though it really came from Purdue, correct?
MR. STRAUBER: Objection.
A. It's a collaborative effort. It's --

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we can't -- we don't impose on any author what they submit. What they submit for publication is submitted from them, by them and totally in their control.
Q. Do you know if Drs. Stanski and Mandema were paid by Purdue?
A. I don't know.
Q. Do you know whether these manuscripts ultimately identified Purdue Pharma as being any part of the author?
A. I don't know. But it was not infrequent that employees of Purdue Pharma would be co-authors on manuscripts. I don't know whether in this case they were.
Q. And then if you'll turn over to page 4 of this document. It says, "Clinical: Status of Core Clinical Program - Robert Reder" -- now, he's the medical --
A. Senior -- senior medical officer on this product.
Q. Okay. "Robert Reder stated that the OC92-1102 study (OA Pain) has been completed and preliminary data is currently being reviewed. It appears that the 10 milligram tablet is similar to placebo in efficacy, but the 20 milligram tablet was significantly different compared to placebo."

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Were you aware that the 10 milligram tablet was similar to placebo in efficacy?

A. I don't recall that. That would not be unusual in any analgesic trial, however.

Q. I'm going to ask you about the meetings of the international R&D meeting. This is -- did we mark that? We did.

This is PDD --

MR. THOMPSON: I'm sorry. We can go ahead and mark it if you want.

PDD1701824723, Exhibit 21.

(DEPOSITION EXHIBIT NO. 21 MARKED)

(Passing document.)

Q. Which appears to -- now we're in November of '94, and present was Dr. R.S. Sackler, correct?

A. If that's what it says, I must have been present for at least part of that.

Q. Then on page 13 --

A. Oh, yes, I was probably present for all of it.

Q. Page 13, third paragraph.

A. Okay.

Q. "Dr. Yeang asked if there were any" --

A. Just a second. I'm sorry. Page 13.

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This one (indicating)? Are you reading from the top here?

Q. Yes, I'm reading from the middle of the paragraph.

A. Okay. Thank you.

Q. About the eighth line down.

"Dr. Yeang asked if there were any statistically significant results. It was confirmed that the 20 milligram product was significantly better than the placebo but the 10 milligram product was not."

Was that brought up at the meeting?

A. It must have been. This is minutes of the meeting, so I'm sure this was -- these minutes were generally of good quality.

Q. If you'll turn over to page 11. And this is shortly before the launch of OxyContin, correct? We're now into November of '90- -- no, it was not. This is over a year before the launch, November of '94.

It says, in the third paragraph, halfway down that paragraph --

A. Yes. Dr. Reder?

Q. Dr. Reder.

It says, "Advantages for OxyContin are

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that not all patients can be successfully treated with morphine and that there is a stigma attached to morphine so far as many patients and physicians are concerned."

And that stigma is what?

A. It's an end-of-life in many hands, principally cancer, drug associated with a whole bunch of negative associations.

Q. Were one of the negative associations side effects addiction, dependency, tolerance buildup?

A. Yes. But that -- the dependency did not differentiate it from any other opioid. It was not more dependence causing or less.

Q. And under this, "In summary, the efficacy of the product has been demonstrated" -- I'm sorry, go to page 12.

A. Okay. Thank you. Okay.

Q. It's therapeutic --

A. Okay. I'm on page --

Q. Third paragraph.

A. From the top or bottom?

Q. Third paragraph from the top. Actually, the fourth. Where it says, "In summary..."

A. Yes. Thank you.

Q. "...the efficacy of the product has

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been demonstrated in six double-blind clinical trials involving 713 patients. Therapeutic conclusions are: The equivalence of 1 milligram of Oxycodone to 2 milligrams of morphine sulfate."

A. That's correct.

Q. All right. No. 2 says, "Equivalence to IR Oxycodone."

A. Immediate release.

Q. Yeah. So they're saying controlled-release is equivalent to immediate-release Oxycodone?

A. The implication here is in terms of potency, I assume.

Q. No. 3 was "The need for dose titration."

A. Yes.

Q. And No. 4 says, "The need for the availability of a rescue formulation." And No. 5 said, "The need for aggressive management of side effects."

Why would you need the availability of a rescue formulation?

A. At this time, and still today, the doctrine of using opioids is to titrate to effect. But in some conditions, cancer and others, the dose

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that has, in general, a good effect may suddenly be insubstantial due to what's called breakthrough pain, and breakthrough pain could be occasioned by movement or trauma or just occasioned by the fluctuation in the pain state.

Rather than maintaining a patient on the highest number of milligrams of any opioid around the clock just to prevent breakthrough pain, the normal practice -- and I think it's the prudent and safest practice -- is to give the patient an immediate-release form ideally of the same analgesic agent that they can take when they have breakthrough pain on an as-needed basis.

Q. Were there studies done at Purdue that showed that blood plasma levels that the medication, instead of lasting for 12 hours really lasted between 8 and 12 hours?

A. There were -- there were blood level studies that showed the profile of blood level, but there is no prediction of what blood level you will need to control what pain. So when we -- what we attended to were the clinical results of treating patients at a 12-hour basis, and that was what we researched.

Now, may I just go on a little bit?

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Q. Sure. Let me ask you this though. What your research actually showed is that OxyContin Controlled-Release provides pain relief somewhere between 8 and 12 hours, correct?

A. I think there were some patients who appeared that way, but principally most were 12 hours.

Allow me to just elaborate just a bit.

Normally people take a Tylenol tablet every -- or two tablets every four hours, but they will get essentially the same effect if they take one tablet every two hours. What we had found was in most patients -- this was found as the drug was marketed -- who complained that at eight or nine hours they were back in pain, yes, they could be treated every three -- three times a day. But if you took that dosage, daily dose, and divided it twice a day, q. 12 hours, they were just as pleased with the pain relief. It was simply that the physician, perhaps by habit or for other reasons, rather than increasing the twice-a-day dose increased the daily dose by telling the patient, Well, take it every eight hours, and it would work fine.

Q. Do you recall Purdue Pharma running into a real problem with their rescue drug because they were trying to decide how to market it and whether to say it was for three to four hours or for six hours, and there was a real debate at the company of how we're going to market this because we're going to hurt ourselves one way or the other depending on whether we say our rescue drug is three to four versus six, because it's the same and you're marketing it two different ways?

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MR. STRAUBER: Objection to the form of the question. It consists of multiple questions and parts.

You can answer it if you can.

A. I have a vague recollection of it. If you could show me some documents -- if you wanted to pursue this with other questions, please show me some documents. I have -- I do have a very hazy recollection of this very minor complication, but perhaps it was a big regulatory complication. I don't remember. I couldn't explain it to you.

Q. So we'll go back to that in a second. He's going to pull something. Let me continue to read from this document.

It says, "Dr. Kaiko reported that bio studies" -- it's the fourth paragraph.

A. Right.

Q. -- "undertaken to show that the 10, 20 and 40 milligram tablets were bioequivalent and dose proportional. In normal subjects it has been demonstrated that at the same total daily dose the controlled-release product given 12 hourly showed the same twofold fluctuation as the immediate-release product given six hourly and that this held across the four-fold dosage range."

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Were you-all aware of that in 1994?

A. I'm not certain what this means. I'm sorry, but I don't know -- I don't know what "two-fold fluctuation" means. I'm sorry.

Q. Did you ask anybody when you were at the meeting?

A. I'm sure I understood it, but I have a -- my -- my best guess is that whoever was taking the minutes somehow perhaps even didn't understand the discussion or may have understood it but wrote it up in a way that doesn't make any sense to me now.

Q. Going down to the fifth paragraph. "A clinical study has been undertaken comparing Oxycodone b.d. versus immediate-release Oxycodone q.i.d. in patients previously stabilized to pain relief."

And then if you drop down, "the study demonstrated that both products maintained baseline

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pain control and pain intensity was the same throughout the day. The acceptability score was the same throughout the study and the same for immediate- and controlled-release products."

And then if you drop down to the next paragraph. "The conclusion from the study was that the 12-hour product was equivalent in efficacy to immediate-release Oxycodone."

And is that why the FDA said other than how many times you take the product being the dosing requirements, there's really not any other benefit?

A. The F- -- I can't tell you whether this was the study that convinced the FDA of that, but it certainly -- it's not -- the finding is completely consistent with that. There may have been other studies that led them to that conclusion with this being just supportive of that conclusion.

In pain studies, I might point out that the biggest advance in measuring pain -- which, of course, is a personal experience. No doctor can look at you and say, Oh, you've got a pain level of 3 and you have a pain level of 6. There's no way of doing it. You have to depend on the patient's report. And the huge advance that led to all the research in

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analgesia and pain relief was called the McGill Visual Analog Scale that was developed in the '50s at McGill University in Montreal. Seventy years later we have no advance on that.

And needless to say -- I suspect everybody in this room has gone to a doctor where they say, "Do you have pain," and if you say -- or to a nurse when they take your blood pressure -- "Yes, I have pain," and they ask you to rate it. That is clearly better than just saying, patient has pain plus, yes or no. But it's not a lot better. It's not terribly -- it's not reproducible and it is highly influenced by the environment and other factors that affect the report the patient gives.

So very often you can compare a highly effective pain reliever to a placebo and you get in the study no difference, and that is widely recognized, and that probably related to the study that you talked about earlier.

The FDA, however, would have required studies that showed a difference, and they did, before they would approve the product. In other words, the negative didn't -- was dismissed as a failed study by the FDA. The positive studies control, because negative studies --

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Q. Do you recall that study being dismissed as a failed study?

A. I don't know that it was dismissed. It was studied. But they must have concluded that that finding is not consistent with either their expectation or ours, or, more importantly, other studies and experience. And clearly the product's success in treating patients in pain, which is indisputable, would put a lie to anybody who would say, Oh, Oxycodone is no better than placebo. I don't think any doctor would assert that. For treating pain, I should say.

Q. Right.

A. Maybe they -- maybe they would say in terms of urinary incontinence it's not effective, but for treating pain.

Q. But whether it's effective or not also depends on other factors, such as abuse. I mean, you can kill somebody and take away their pain, but that certainly wouldn't be effective, would it?

A. I don't think that death would be considered a sign of efficacy.

Q. Correct.

A. Yes -- I mean, in the extreme, yes, what you said is correct.

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Q. So just because it takes away pain doesn't mean it's a good drug, does it?

A. No.

Q. All right. Let's look at Sackler Exhibit 13 again. I did want to ask you one question about this.

A. There's always a balance between effectiveness -- I'm sorry. There's always a balance between effectiveness and safety.

Q. If you go to page 4, 1.4. It says, "If physicians perceive OxyContin as controlled-release Percocet, it is likely that they will start to use it in place of Oxycodone combinations. As physicians become more comfortable with the use of the Oxycodone combination market, it is possible they will start to use OxyContin in place of Class III hydrocodone or codeine combination drugs."

And Class III are not as regulated as Class II, correct?

A. That is correct.

Q. "Therefore, it is imperative that we establish a literature to support such use."

Who at Purdue Pharma was trying to establish a literature to support a Class III use for

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OxyContin?

MR. STRAUBER: Object to the form of the question.

A. Your -- the answer to your question is nobody. We had no plan, program or expectation that -- or intention to change OxyContin from a Class II to Class III. In fact, it is not too long ago the FDA has reclassified Oxycodone as a Class II drug.

Q. Okay. So you think that -- where it says, "Therefore, it is imperative we establish a literature to support such use" is referring to physicians believing where it says "Physicians perceive OxyContin as controlled-release Percocet, it is likely they will start to use it in place of Oxycodone combinations"? Is that what that development of literature is referring to in your opinion?

A. Probably, yes.

Q. Who -- who was --

A. I don't know.

Q. -- trying to develop that literature?

A. I don't know. That would have been a combination. That would have been the medical department to do studies and then have them published.

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That would have been a research effort.

Are we finished with this one?

MR. STRAUBER: Off the record. In between subjects, would now be a good time to break for lunch?

MR. THOMPSON: Yes.

VIDEOGRAPHER: We are off the record. 1:11 p.m.

(RECESS)

VIDEOGRAPHER: We are back on the record at 2:03 p.m.

BY MR. THOMPSON:

Q. All right. Dr. Sackler, picking back up after our break. We've taken a number of breaks, but I'll just remind you, any time you need to stop or need a break, just let us know --

A. Thank you.

Q. -- and we'll stop again.

We were talking earlier about this issue with rescue OxyContin. And let me hand you what we're going to mark as Exhibit 22.

(DEPOSITION EXHIBIT NO. 22 MARKED)

(Passing document.)

Q. And if you go back to the last page, there is a memo dated 9-21-95 from Robert Reder,

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R-E-D-E-R.

A. Yes.

Q. And he says, "Currently our draft PI" -- that's package insert, correct?

A. Yes.

Q. -- "and, therefore, our sales material have the same dosing of rescue as q. 3-4h p.r.n."

And that is -- means what?

A. It means every three to four hours as needed.

Q. Okay. And do you know if the people who were involved in the studies of OxyContin were given OxyContin for rescue pain?

A. OxyContin?

Q. Yes.

A. Or you mean Oxycodone?

Q. Oxycodone. I'm sorry.

A. I'm sorry. I don't know.

Q. It says, "BK brought this issue up some time ago. It is now surfacing again because of the review of our sales material. OxyIR" -- and is that Oxycodone?

A. Yes.

Q. -- "is being promoted as rescue q. 3-4h."

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And that's every three to four hours, right?

A. That's correct.

Q. He said, "While this may be consistent with the OxyContin package insert if it is approved as stands, it will be inconsistent with the OxyIR 5 milligram package insert which uses q. 6h," meaning you take it every six hours, correct?

A. That's what it means.

Q. He says, "Moreover, if we use the q. 3-4 hours, it will help to validate Roxane's change in their package insert."

What was the reason that you-all did not want to validate Roxane's change in their package insert?

A. I -- I would have to read this completely and try to answer your question, but I'm not sure this will prompt me to remember. May I?

Q. Sure.

A. I really don't remember this well enough to answer your question.

Q. Well, let me continue reading here. It says, "Finally, it creates a problem for the OxyIR 10 milligram and 20 milligram capsules as the package insert would have two different dosing intervals

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depending upon the use, i.e., q. 4 for rescue and q. 6 for usual pain use."

He says, "One suggestion would be to make everything consistent at q. 6 hours. Rescue would then be q. 6 p.r.n." -- as needed -- "as would some acute pain prescriptions. For ATC use, it would be just q. 6 hours.

"Although I hate the thought of recommending a PI change" -- package insert change -- "I understand FDA may recommend a change or two such as removing the plasma curve graph. At this point we could change the frequency of dosing in the PI. What do you guys think?"

So what he's saying here is, we've got the exact same drug, we've marketed it for two different purposes, and we've got two different dosing regimens for the exact same drug, correct?

A. It seems to suggest that, but I can't confirm it.

Q. And then Paul Goldenheim -- if you turn to the next page and read the next one at the bottom -- says -- and who is Paul Goldenheim?

A. He was head of R&D, research and development and medical.

Q. He says, "The issue that won't go away. Robert is right, we need to discuss again. Robert, please arrange a meeting. Round up the usual suspects. This is too complicated for e-mail."

Then Friedman -- and what was his role?

A. He was head of marketing and sales.

Q. The head of marketing and sales writes back and says, "Is it unreasonable to have a q. 6h dose" -- meaning take it every six hours -- "for normal dosing and a q. 3-4 hour for rescue?"

So the marketing guy is saying, Well, hey, can't we just take the exact same medication and say if it's for a normal dosing, take it every six hours, but if it's for rescue, take it every three to four hours?

A. That's what he says. And what he meant was for normal around-the-clock dosing rather than rescue, which is one or two or three doses and that's it, as needed.

Q. And then up at the top you write back and say, second one down, "I agree, this is too complicated to solve through written exchange. Paul, I think that you should get us together soon. Good pickup someone."

Do you recall writing that e-mail?

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A. No, but it looks like I wrote it.

Q. Okay. And then Robert Kaiko writes back and says, "Unfortunately soon may be too late. Robert? As previously" -- so he's saying I brought this up again.

"As previously, I recommend we change everything to q. 6 hours for immediate-release Oxycodone products."

And he is the head of what, Robert Kaiko?

A. He was in the medical department and he was the project -- the research project head for the overall OxyContin project.

Q. Okay. So he's saying, it appears to me, maybe perhaps to be a little frustrated and saying --

A. I don't know.

Q. -- "Soon may be too late. As previously, I recommend we change everything to q. 6 hours"?

A. I can't say why he wrote the first sentence, whether he was frustrated or whether he was actually referring to some sort of deadline, maybe in a clinical trial, maybe on submissions to the FDA. I don't know why.

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Q. But at least from the appearance of this, you've got Friedman, the head of marketing, saying why don't we take the same product and just say take it every six hours, and if it's for rescue it's good for three or four hours?

A. Right. This -- essentially to fill in the blank here, what his -- what he must have meant was, have two indications. For regular use of immediate-release Oxycodone, administer it around the clock every six hours; for rescue use, administer -- you can administer the dose every three to four. But that wouldn't be indefinite, this would be for rescue for breakthrough -- actually for breakthrough pain.

Q. And Friedman, the head of marketing, is not a physician, correct?

A. That's correct. So he's making a suggestion.

Q. Dr. Robert Kaiko, the head of the project for Oxycodone, is a physician, correct?

A. He is.

Q. And he's saying, don't do what Friedman's saying, we need to make it q. 6 hours for immediate-release Oxycodone products, correct?

A. First of all, Friedman asks a question here. He's not asserting a proposition, he's asking,

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explain to me why we can't do this. And I understand why he asks the question. And the only answer could be it would -- it might be confusing to a physician, but I think the emphasis should be on "might be confusing."

Q. And then you write back the next day and say, "I don't know how urgent this is. If it can't wait until tomorrow, let us know immediately. I don't have a problem with this change at all. Does anyone question it?"

And who is Mr. Alfonso?

A. He was head of marketing at the time.

Q. Okay. So the head of marketing comes back and he says, "The way these drugs are written are q. 4-6. The rescue is for q. 3-4 hours." And he explains, "The problem might be that if we go the q. 3-4 hour route, we will validate the Roxane dosing..."

Again, I'm going to ask you, do you know what the problem was what validating the Roxane dosing and why he thought it was a problem?

A. I don't remember. I don't really think it was a problem. I can't imagine what he was thinking of.

Q. Okay. So he writes, "The problem might be that if we go the q. 4 -- q. 3-4 hour route,

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we will validate the Roxane dosing and possibly present a challenge to the OxyContin studies."

So if he's validating the Roxane with the q. 3-4, would it appear that perhaps the Roxane had required -- now, that's an overseas company, correct?

A. No. Roxane was an American company, I believe, at that time owned by Boehringer-Ingelheim.

Q. Okay. Did they -- did they put a dosing limit on OxyContin to your knowledge?

A. Oxycodone you mean?

Q. On Oxycodone.

A. No, not to my knowledge. I don't think it was an issue of limit.

Q. Do you know what Roxane's dosing was that he's referring to?

A. No.

Q. So he says, "The problem might be that if we go the q. 3-4h route, we will validate the Roxane dosing and possibly present a challenge to the OxyContin studies. On the other hand, a much more dangerous scenario can occur if we go the q. 6 hour for maintenance and rescue. If we go this route and price continues to be a major issue when we narrow the value of OxyContin closer to the IRs" -- and that's

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immediate releases? Is that what that is?

A. Yes, IR would be immediate releases. I'm just reading the sentence because I'm not -- I didn't follow what it meant.

Q. He says -- the next sentence says, "In essence if you can use an IR q. 6 hours at a cheap price, then those doctors that use OxyContin q. 8 hours (there will be some regardless of what we say or do) will not see a benefit over the immediate releases. In addition, our promotional campaign has a visual, six cups representing q. 4 hours. If we go q. 6 hours, we will -- might have to change the visual to four cups, and this will not have as much impact. We need to go q. 6 hours for maintenance and q. 3-4 hours for rescue so that we can maintain the integrity of our OxyContin studies."

Did I read that correctly?

A. You did.

Q. Do you know whether you went q. 3-4 hours for rescue and 6 hours for maintenance?

A. I don't know.

Q. All right. Let's -- let me jump back. I'm going to hand you this document.

(Passing document.)

MR. THOMPSON: Why don't we go ahead

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and mark that as Exhibit 23.

(DEPOSITION EXHIBIT NO. 23 MARKED)

Q. This is from you dated April 20th, 2000.

So OxyContin has been on the market over four years at this point, correct?

A. Yes.

Q. And under No. 5 it says, "OxyContin Tablets price increase is the central decision. Every 0.1 percent is 1M" -- I'm assuming that's one million?

A. That's correct.

Q. -- "one million to the bottom line. What would the risk of having a 4 percent increase instead of a" -- "what would the risk be of having a 4 percent increase instead of a 3 percent increase?"

And you're talking about price increase, correct?

A. That's correct.

Q. "Our average realized price is constant, suggesting that rebates and other discounts are taking a larger share of our business. 3 percent annual notional increases seems to hold our per KG" -- is that kilogram?

A. Kilogram.

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Q. -- "price constant in an environment where many prices are going up."
Was it true that every time you increased the price 0.1 percent you added one million to the bottom line of Purdue Pharma?
A. I don't remember. The answer is no to your question. I don't remember whether this is correct or not when I wrote it, but it certainly wouldn't have been correct every time.
Q. We were talking earlier about Purdue Frederick versus Purdue Pharma. Did you ever determine whether the employees -- the sales force that engaged in improper conduct as referenced in the felony plea agreement were employees of Purdue Frederick or employees of Purdue Pharma?
MR. STRAUBER: I object to the form of the question. I don't think it accurately reflects the plea agreement.
A. Could you just restate the question because I kind of lost the thrust?
Q. Sure. Did you ever make a -- we've talked about Purdue Pharma and Purdue Frederick. Did you ever make a determination whether the employees who engaged in illegal activity as referenced in the felony plea agreement -- or improper activity as

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referenced in the felony plea agreement were employees of Purdue Frederick or employees of Purdue Pharma?
A. I'm not aware of whether such a study was done or anybody focused on that question that may have been done. But you should be -- you should think of this, that the felony plea agreement came years after many remedial actions had been taken to retrain everybody, to discipline, sanction -- correct, discipline, sanction or dismiss employees who had behaved improperly, and those processes which started late in 2000 or early 2001 continued right up to the plea agreement and then after the plea agreement.
Q. Sure. Have you looked at the call notes of the reps in Kentucky?
A. I have not seen any except those that were showed to me during my preparation. There were three or four that I saw.
Q. Did you review the documents that Mr. Shapiro, the lawyer that you-all hired, put together for the U.S. attorney in Virginia?
A. I don't think so. Those don't seem familiar to me.
Q. And that was the attorney that you-all hired to defend you in the case brought by the U.S. attorney in Virginia; is that correct?

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A. Yes.
Q. You-all paid him approximately 50 million dollars to defend you in that case -- or paid his firm approximately 50 million dollars to defend Purdue in that case?
A. I'm -- I can't verify. That's the first time I've heard a number attached to that.
Q. If he testified to that, would you dispute it?
A. I would have no basis to dispute it.
Q. And do you know if anybody at Purdue made an effort to determine whether the submission and the call notes that were pulled by the lawyer hired to represent you were accurate or not?
MR. STRAUBER: I object to the form, because I don't know how anyone knows what it is you're referring to.
Q. Are you aware that he made a submission on behalf of Purdue to the U.S. Attorney's Office?
A. I am not aware of anything that he submitted to the U.S. Attorney's Office.
Q. You've not reviewed any of the materials he submitted to the U.S. Attorney's Office when he was defending Purdue?

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A. I did not.
Q. Were you aware of the call notes that he pulled and purported were evidence of improper behavior on behalf of Purdue salespeople?
A. No.
Q. Did anyone at Purdue, to your knowledge -- Purdue Pharma or Purdue Frederick -- make any attempt to ascertain what percentage of reps in Kentucky were engaging in the type of behavior that the plea agreement says was improper?
A. I'm not aware of that.
Q. Did you ever instruct anybody to do it?
A. To do? Could you be more precise, please?
Q. Did you ever instruct anybody at Purdue to undertake an investigation to find out what percentage of reps in Kentucky, and which ones, were engaging in conduct that was referenced as improper in the felony plea agreement?
A. No, I did not.
Q. Have you reviewed Howard Shapiro's deposition in this case?
A. I have never seen it.
Q. He was asked -- let me read this

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question and his answer.

"Mr. Shapiro, before the break, we were discussing the agreed statement of facts, and specifically paragraph 20. One of the questions that I asked you previously about the conduct described in the agreed statement of facts was, did you ever figure out who the employees referenced in the agreed statement of facts worked for, was it Purdue Frederick Company, was it Purdue Pharma, L.L.P., or some other entity?

"With respect to the employees we've been discussing -- and those are employees whose conduct is described in paragraph 20 and its various subparts -- did you ever do a determination to determine whether those employees were employees of Purdue Frederick Company who signed the agreed statement of facts or some other Purdue entity?"

And his answer is, "Without going into too much work product, let me state we did sufficient investigation once -- once it turned this direction to satisfy ourselves and our client that there were Purdue Frederick employees who engaged in the conduct that's referenced in here and that forms the basis for the guilty plea."

"Question: Were there any employees

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of Purdue Pharma, LLP that are referenced here or any other Purdue entity?"

"Answer: Well, again, and I'm -- just what I said before, the -- I don't know whether at -- at which point in time Michael Friedman hired Udell, Paul Goldenheim, whether they were Purdue Pharma or Purdue Frederick or some of the -- some of them had been one and then the other. Beyond them there were -- when we looked, for instance, at the names that are associated with the -- in the first supplemental responses to whatever that was, 23, I think."

Now, did you understand that answer?

MR. STRAUBER: Mr. Thompson, I object to the question. Plus, could you let the witness have a copy to read, as it's very hard to follow when you're reading such a lengthy --

MR. THOMPSON: Sure.

MR. STRAUBER: -- series of questions and answers.

MR. THOMPSON: Do we have another copy of this, Tony?

Q. Here. I'll tell you what, you can just read along with me, if you want to do that, and I'll hold it over here.

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A. No. I think he would like to see it.

MR. STRAUBER: I'd like to see it also. Plus, he really can't see that distance physically.

MR. ELLIS: We'll print off some copies.

MR. THOMPSON: Why don't we go off the record while we get some copies of this.

VIDEOGRAPHER: We are off the record at 2:28 p.m.

(RECESS)

VIDEOGRAPHER: We are back on the record at 2:29 p.m.

Q. Sure. And to save time, I'll let you read it. Can you start with the next question, which was "Uh-huh" and read the answer.

A. Read the answer. The "Uh-huh" doesn't really set up the answer for me.

MR. STRAUBER: That's page 214, line 27, the "Uh-huh."

THE WITNESS: 2017?

MR. STRAUBER: Yes, I'm sorry. Page 2 --

THE WITNESS: 214.

MR. STRAUBER: -- 14, line 17.

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THE WITNESS: Right.

MR. STRAUBER: Okay.

A. "Uh-huh" is the question.

"Answer: Of people who are referenced but not named in some of the paragraphs, I don't believe that we made any effort to determine whether at the relevant times they were Purdue Frederick Company employees or Purdue Pharma employees."

Q. Okay. And is that testimony accurate?

A. I can't -- I can't vouch that it's accurate. It's consistent with my knowledge.

Q. So the next question says, "So it could have been either or one or both."

A. Yes. The question is, "So it could have been one or either or both; you're not sure?"

And the answer is, "Correct."

Q. Yeah. Now, in 2001, who did Michael Friedman work for?

A. I don't know.

Q. You don't know if he worked for Purdue Pharma in 2001?

A. My best guess is he worked for Purdue Frederick, but it's a guess, and maybe for Purdue Pharma, but I don't really know.

Q. How about Howard Udell, do you know

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who he worked for?

A. No.

Q. What about Paul Goldenheim, do you know who he worked for?

A. I don't -- I don't know that.

Q. Do you know whether you worked for Purdue Pharma or Purdue Frederick in 2001?

A. I don't know for sure.

Q. So going back to our OxyContin launch team. I'll hand you that.

(Passing document.)

A. Do you want to put a number on this?

Q. Yes. Let's mark that as Exhibit --

A. 25?

Q. -- 25.

A. No.

COURT REPORTER: 24.

(DEPOSITION EXHIBIT NO. 24 MARKED)

Q. And I've just got a couple of paragraphs I want to ask you about.

A. Sure.

Q. So on -- this is dated April 4th, 1995, and it says at the first paragraph, second sentence, "Mike Innaurato" --

A. Oops. First paragraph on which page?

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Q. I'm sorry. Page 1, second paragraph.

A. Oh, second paragraph. Okay.

Q. "Mike Innaurato" -- he's the marketing guy again, correct?

A. Yes.

Q. -- "discussed the marketplace that OxyContin will enter and how OxyContin will expand out of the cancer pain market. OxyContin will be launched in 10, 20, 40 milligram tablet strength, 80 and 160 milligram tablet strength to follow."

And if you go on down a little bit further, he says, "OxyContin will be indicated for the relief of pain with the convenience of q. 12 dosing. OxyContin's primary market positioning will be for cancer pain and the secondary market will be for non-malignant pain, musculoskeletal injury and trauma. It was reinforced that we do not want to niche OxyContin just for cancer pain."

And was it part of your-all's marketing strategy not to niche OxyContin for cancer pain?

A. Not to limit it, yes.

Q. Below that it says, on the last paragraph, "In our market research efforts, focus groups, personal one-on-one interviews and telephone

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interviews were conducted with more than 500 healthcare professionals. In our focus group findings we learned that MS Contin" -- that's the drug that you already sold, correct?

A. I'm sorry, I didn't hear the question.

Q. That's morphine sulfate, correct?

A. Yes.

Q. That's the one that you had not had any reports of abuse or diversion with that you could recall, correct?

A. None that I was aware of, yes.

Q. And it says, "We learned that MS Contin is the gold standard for cancer pain. Our creative concept testing showed the likelihood of OxyContin usage by physicians and nurses were 4.6 on a scale of 1 to 5, which is very favorable."

Were you aware of this creative concept testing and focus groups that were being conducted?

A. I don't recall.

Q. And then if you go to the next page, page 2, last paragraph. "Our meeting ended with a question and comment period. Michael Friedman emphasized the threat that AB-rated generics posed to MS Contin. We're not sure when AB-rated generics will

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be launched, but we don't think it will be until 1996. Inevitably the AB-rated generics will arrive and this is why it is extremely timely importance that we must establish OxyContin. OxyContin can cure the vulnerability of the AB-rated generic threat, and that is why it is so crucial that we devote our fullest efforts now to a successful launch of OxyContin."

Were you aware that was part of the strategy?

A. I'm sorry, but what was part of the strategy?

Q. That the AB-rated generics were going to arrive and that is why it was extremely timely importance -- that's the way it's written -- that we just establish OxyContin and it was crucial to devote the fullest efforts to a successful launch because of AB-rated generics?

MR. STRAUBER: Objection to the form. The witness can answer.

A. Yes, I was aware of that. And the reason is clear. MS Contin was our most important product at that point, and when the sales were eroded by generics, we would have -- if we had not replaced those sales with other product sales, we would have a much smaller company. That would cost many people

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their jobs.

Q. Are you familiar with the OxyContin Product Team?

A. I've become reminded of it, yes.

MR. THOMPSON: Let's mark this as Exhibit -- is it 25?

COURT REPORTER: 25.

(DEPOSITION EXHIBIT NO. 25 MARKED)

(Passing document.)

Q. And this is minutes of the OxyContin Product Team dated -- the meeting was February 22nd, 1996 up at the top.

A. Washington's birthday.

Q. It says, first paragraph, "The OxyContin Product Team met on Friday, February 22nd, 1996, and topics of discussion included the following:" Number one is "Marketing's wish list for clinical studies," and then it's got a list of studies. Number one is "Postoperative pain to support the Abbott agreement."

Why did you need studies on postoperative pain to support the Abbott agreement?

A. I don't recall.

Q. "Pharmacoeconomic." What was the reason for pharmacoeconomic studies being needed, if

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you recall?

A. I don't recall that circumstance.

Q. And then it says, "Non-malignant pain (example, functional improvement)." And then the subcategories are "Low back pain; osteoarthritis, long-term safety data."

A. Right.

Q. Why did you think that marketing needed -- was needing on March 7th, 1996, after the product had already been launched, long-term safety data?

A. I don't remember precisely. But all studies would include or would enhance the data available to support long-term safety if the studies were long term. And the studies that were referenced here, low back pain and osteoarthritis, would surely have been long enough to add to that database.

Q. Then can you explain why the head of the OxyContin -- or the OxyContin Product Team on February 22nd, 1996, after the product launch said we need long-term safety data?

A. I don't think there was any question about the safety of the drug. It was just an addition that it would enhance the dossier that was available.

Q. Do you --

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A. I don't know how you would do a long-term safety study devoid of some condition, so the long-term study would be focused on following a condition, that's low back pain or osteoarthritis. And at that time the studies were typically 12 weeks and with an open extension at the end they could go on for a year.

Q. That is a subcategory of non-malignant pain, correct?

A. These two studies, low back pain and osteoarthritis. Long-term safety would be a general concept that would apply to any kind of study that's long enough to accumulate that data.

Q. They've included long-term safety data under their marketing wish list under non-malignant pain, correct?

A. They did.

Q. So it looks like they're saying we need long-term safety data on prescribing OxyContin for non-malignant pain.

Do you read that the same way or differently?

A. I -- I guess I read it differently than you do. Just that it wasn't that we needed it, it was a wish list. But it was inherent in any

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long-term study we did of any pain condition.

Q. And then we talked about the FDA's statement about comparative studies. Do you remember that, where they said you should refrain from comparative analysis?

A. I don't remember. So if you could just go forward with the question, that would be great.

Q. Sure. One of the things that the OxyContin marketing team's wish list has under No. 5 is "Comparative studies, especially versus: Combination opioids such as hydrocodone combinations, Duragesic, MS Contin, Kadian and Ultram NSAIDS."

Those are nonsteroidal antiinflammatory drugs; is that right?

A. Ultram is an opioid drug. NSAIDS are nonsteroidal antiinflammatory drugs.

Q. Right, NSAIDS.

A. So they're not the same. I don't know why they were -- the bullet put them together, but they're different.

Q. Right. No, no. I get it. I'm asking you, is that what NSAID stands for, nonsteroidal?

A. Yes.

Q. Has that been marked?

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A. That's been marked 25.
Q. All right. Now, let's go to the launch plan. And this is dated September 27th, 1995. And if you'll go to page 42 of the launch plan.
(Passing document.)
Under 5.851 under "Public Relations" at the top it says, "The objective of the public relations campaign is to create broad awareness of the launch of OxyContin. This awareness will be directed at the consumer and healthcare professionals through various media channels, such as print, TV and radio. In an effort to create a 'media hook' that would coincide with the launch of OxyContin, a consumer survey conducted by a company such as the Gallop Poll is being proposed. This survey would focus on the prevalence and problems of chronic pain, both malignant and nonmalignant. The release of the results of such a survey would be publicized along with the recent FDA approval of the new controlled-release Oxycodone preparation OxyContin. This is a classic problem/solution strategy to create a need for the launch of a product such as OxyContin."
Did I read that correctly?
A. You did.
Q. Do you know if a poll was conducted by someone such as the Gallop Poll?
A. I don't know what the poll is precisely.
Q. Then -- then the next paragraph says -- 5.852. It says, "In an effort to continue the publicity about the launch of OxyContin, approximately two to three months after the initial public relations campaign, another campaign would be launched focusing on the expansion of Purdue Frederick's Partners Against Pain Program developed to improve pain management knowledge among healthcare professionals and patients' caregivers."
Partners Against Pain was a creation of Purdue Frederick, correct?
A. That's what it says.
Q. And there were no partners, correct?
A. No, I think there were partners, the meaning of the campaign.
Q. Who do you think the partners were?
A. Physicians, nurses. Other healthcare workers are partners.
Q. Oh, okay. So -- but as far as setting it up, there weren't any other partners involved in setting up Partners Against Pain? I mean, the government wasn't involved in Partners Against Pain, other healthcare companies weren't involved?
A. I don't know whether other healthcare companies were involved, but the government would not have been involved in setting up this program.
Q. And it says, "This campaign would reiterate the prevalence and problems uncovered in the consumer survey and explain how Purdue Frederick has made a commitment to improving the level of care for patients suffering in pain. In addition, the campaign would expand the recent launch of Purdue Frederick's newest partner against pain; OxyContin."
MR. STRAUBER: Excuse me. I think you just made an error in reading. "It would explain" not "would expand."
MR. THOMPSON: I thought I said "explain."
Q. And then the next paragraph says, "In addition to the above public relations campaigns, we are exploring the possibility of Purdue Frederick sponsoring a pain management foundation in association with an organization such as Gilda's Club."
Do you know if you sponsored a pain management foundation?
A. I do not, but I -- no, I don't -- I don't know if we did that. I don't think we did, but that's a vague recollection.
Q. Can we agree that the main way you marketed and promoted OxyContin was with your sales force?
A. Yes.
Q. And those are the people that actually go out to the physicians' offices and pharmacies and to the communities and sell OxyContin, correct?
A. They don't actually sell, but they promote OxyContin. The distinction being that they don't actually take orders and arrange deliveries and collect any money.
Q. Okay. And you would consider them the most valuable resource that Purdue had to sell OxyContin, correct?
A. It was the most valuable resource that we used. We thought it was the most efficient resource and that's why we used them. Whether other approaches or resources would have been more valuable, I can't say.
Q. At some point did you figure out that the key to getting physicians to prescribe and keep prescribing OxyContin was through regular visits from the sales force?
A. That would be typical of any

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pharmaceutical sales force, yes.
Q. And was there a realization that developed that certain physicians, so-called core physicians, were more likely to prescribe OxyContin?
A. I'm not sure. It wasn't -- I think it was the other way around. Our most significant prescribers were called core, not that we identified a core and then they became important prescribers.
Q. And how many companies were sending sales representatives to physicians' offices to talk to them about opioids during this time?
A. Three to five. It's a guess on my part. I don't recall any survey that counted that up. But it's a guess based upon my recollection of what was being actively promoted.
Q. And you compensated your sales force very well based predominantly on how much OxyContin they sold; is that correct?
A. The successful -- the most successful salespeople, a majority of their income was bonus. The average salesman, certainly when we launched the product the overwhelming majority of their income was their salary and the benefits that they received. And for the average sales force -- salesman, I think it would have been 50 percent of their income or 70

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percent of their income salary and the balance in bonus.
Q. Sure.
A. But I don't -- I don't remember this in detail. And, of course, it changed over time.
Q. The way the sales scheme was set up, if they sold more OxyContin, they made more money, basically?
A. Yes. Yes. The same as almost every other company in the industry.
Q. And then you-all gave your reps an additional incentive because you decentivized them to sell MS Contin but you increased the incentive for selling OxyContin; is that true?
A. Yes.
Q. And then you had one of the highest paid sales forces in the country; is that accurate?
A. I've heard that said for one or two years. It certainly wasn't the case or hasn't been the case during the history of OxyContin.
Q. Do you know if reps that promoted and sold OxyContin sometimes ended up making over $250,000 a year?
A. I've heard that that was the case. I'm sure it was unusual.

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Q. And then your top sellers were rewarded with trips to Bermuda or London in what was called the Toppers Program; is that correct?
A. Yes.
Q. And during the first five years of OxyContin's release, Purdue more than doubled the size of its sales force, correct?
A. That's correct.
Q. And do you know how much of the sales force during the first five years was Purdue Frederick versus Purdue Pharma employees?
A. I don't know.
Q. At some point were some people designated -- all new hires designated Purdue Pharma as opposed to Purdue Frederick?
A. I believe that that's the case.
Q. But you're not sure what date that started?
A. No.
Q. Do you know if it was after the creation of Purdue Pharma that that started?
A. It would had to have been. If Purdue Pharma didn't exist, we couldn't have hired somebody.
Q. Right. But, I mean, was it immediately after that that all -- once it was created

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all reps were hired by Purdue Pharma as opposed to Purdue Frederick?
A. I don't know.
Q. Who would know that at Purdue?
A. I don't know. At Purdue now?
Q. Yes.
A. At Purdue Pharma you mean?
Q. Yes.
A. Well, the people who were there at that time might recall it, but I don't know who today would know it.
Q. And then in addition to targeting or providing initiatives to the sales force, you also targeted wholesalers, correct?
A. Wholesalers were called upon by the salesmen, yes.
Q. And, in fact, I think if you go to page 27 of the initial launch plan -- let's see if I can find this -- the last paragraph. It says, "All promotional efforts for the retail distribution of OxyContin will focus on the incredible success that Purdue Frederick has achieved and sustained with the MS Contin product line. Wholesale pharmaceutical buyers and retail pharmacists should be reminded of how MS Contin created such a large market for the use

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of sustained-release opioids for the treatment of pain. This in turn created profits for pharmacists helping to grow their businesses. Promotional copies should focus on the market potential for OxyContin and patient populations to be targeted, including the number of prescriptions written for Class II and Class III opioids every year.

"The executive director of national accounts should work with drug wholesalers in developing programs to utilize the wholesaler sales representatives to ensure adequate distribution. Consideration should be given to advertisements in drug wholesaler ad books and computer programs."

Were the sales force told to emphasize with pharmacists that they could make more money with OxyContin prescriptions?

A. I don't think that they would have been encouraged to say that. The objective when any product is launched, and certainly any medicine is launched, is to be -- is to minimize the number of times a patient -- number of patients who get prescriptions from their doctor and go to the pharmacy and the pharmacist says "I don't have that" or, even worse, "I never heard of that," for obvious reasons.

So in order to reduce that, one tries

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to stock all three strengths in as many pharmacies as possible. But to begin with, there's no demand. So there's a bit of tension there. In order to supply the pharmacists, the wholesalers have to have enough stock on hand for the ones who buy it early and a sufficient backup stock both to supply the early buyers and the later adopters. And that was all that we needed to accomplish and there's not much more I can say about it except that however we did it was ethical and proper.

Q. And let me go back to my question. Where it says "Wholesale pharmaceutical buyers and retail pharmacists should be reminded of how MS Contin created such a large market for the use of sustained-release opioids for the treatment of pain. This in turn created profit for pharmacists."

Am I reading that incorrectly somehow that --

A. You're reading it correctly.

Q. What you're telling -- what this launch plan, sales force -- under the title "Sales Force Allocation and Representative Delivered Promotional Materials" is saying, hey, remind them they're making a bunch of money selling our product?

A. As opposed to not selling any product.

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Q. It says, "A cooperative direct mail advertising sales sheet offering a rebate on the initial order of OxyContin to retail pharmacists will be mailed every month during the first three months of launch."

What was the rebate you-all were offering to pharmacists?

A. Some discount on their early orders to encourage them to stock the product in advance of seeing any prescriptions or one or two prescriptions. And like the rest of -- there was nothing innovative in this program. This is -- this was standard programming in the pharmaceutical industry and in other industries.

Q. Well, some of your other literature talks about you-all had an unprecedented marketing campaign.

Have you ever seen another company that instituted a more broad-ranging marketing campaign than you-all did for OxyContin?

A. I think this was conventional. Unprecedented perhaps for us, but not unprecedented in the industry. This would -- this is conventional standard textbook. This is how you do it.

Q. All right. You-all also were involved

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with third-party organizations, Partners in Pain. They were referenced in the launch campaign. And did you use Partners in Pain to drum up demand for OxyContin?

A. No. I -- I think that Partners in Pain was principally designed to inform doctors about the proper use of our drugs, our medicines, and to encourage patients who may have had pain, sometimes for years, inadequately treated or not treated at all to present themselves to their physicians.

Q. There was also -- Purdue funded a variety of so-called pain societies. The American Pain Society, was that funded by Purdue Pharma?

A. We donated money to the American Pain Society.

Q. Did you also fund the American Association for Pain Management?

A. If -- it wouldn't surprise me. I don't remember.

Q. Did you also fund the Appalachian Pain Society?

A. I don't know that, and I wouldn't have known it. But if that's what the record shows, it wouldn't surprise me.

Q. There was a figure we looked at a

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while ago that said there was -- basically the target market for physicians was about 7,500 physicians, including the cancer, malignant pain and the non-malignant pain across the U.S. Do you remember seeing that?

A. No.

Q. Do you think the market was more than 7,500 physicians --

A. Much larger.

Q. -- for pain?

A. Much larger. Pain is the most common presenting symptom for physicians in total, and very few physicians would have a different experience. Perhaps ophthalmologists or dermatologists may, but every other physician it would be the most common or the second most common presenting complaint.

Q. Do you recall whether Purdue Pharma set up a speakers bureau in which it allowed physicians who were recommended by salespeople to be put on the so-called, quote, speakers bureau?

A. They -- yes, such a program existed. Not everybody who was recommended was put on the speakers bureau. They were vetted by internal experts to determine their qualifications.

Q. Do you recall that there were over

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3,000 physicians on the speakers bureau?

A. I don't recall it, but it wouldn't surprise me.

Q. Do you think somebody vetted all 3,000 physicians internally that were on the speakers bureau?

A. We had quite a large organization to do that and to manage the speakers bureau. So I think everyone was -- should have been vetted. There was -- there was no excuse for not validating their degrees and confirming that they were licensed to practice in the place that they were practicing and so forth. I don't know precisely how they were vetted, but they definitely should have all been vetted.

Q. Do you think putting these 3,000 doctors on your speakers bureau caused them to write more prescriptions for OxyContin or less prescriptions for OxyContin?

A. I don't think it would have had an effect.

Q. And there were also individuals -- you started a program called Train the Trainers where you would fly physicians around the country to speak on behalf of Purdue. Do you recall that?

A. Actually, the -- the physicians who

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attended and spoke were trainers, and some of them were in-house people and some were outside physicians.

Q. And would these take place at resorts, like in Florida and Arizona, these meetings?

A. Certainly might have.

Q. And you also --

A. But -- but -- but to my knowledge, I don't think anybody would go more than once, and they were trained in what they could say, what they couldn't say, and they were given materials to use in the presentations, for a while slides and then I guess eventually PowerPoint presentations. So it was to create some control to see, hopefully, that they would not go off label.

Q. And did Purdue pay for that, or did they pay their own way?

A. At the time it was started, Purdue paid for it. This was, again, customary in the industry.

Q. Who told you that was customary in the industry?

A. I don't remember who told me. But I can tell you that sometimes I'd go to hotels and I'd see events sponsored by Pfizer or sponsored by J & J, and they were precisely -- either they were speaking

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engagements in which somebody spoke, and occasionally they were Train the Trainer kind of ideas where the company in question -- other companies in that case -- trained physicians, you can say this and this and this, beware you shouldn't say that and that and that.

Q. Do you know whether pharmaceutical companies and medical device companies have come under criticism for giving incentives for doctors to write prescriptions or use their medical devices?

A. I'm aware of that.

Q. And the answer is, they have come under criticism for that?

A. Yes. I...

Q. Was Russell Portenoy one of the speakers that spoke on behalf of Purdue Pharma at these meetings?

A. OxyContin?

Q. Yes.

A. I don't know.

Q. In addition to the stuff we've just talked about, you also hired a number of third parties to assist in the marketing of OxyContin, such as marketing firms, correct?

A. I don't know.

Q. Do you know if Purdue retained Lyons

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Lavey to market OxyContin?
A. I've heard the name, but I don't know that it was OxyContin.
Q. Do you know if public relation firms were also hired to assist in the marketing and the expansion of the market --
A. I don't know.
Q. You've got to let me finish my question.
A. I'm sorry. Excuse me.
Q. That's okay. We've got a video, but we also have a court reporter/stenographer taking it down.
A. I'm sorry. Apologies.
Q. She can't get it if we both talk at the same time.
So my question is, do you know --
MR. THOMPSON: Can you read my question back?
(Record read.)
Q. -- for OxyContin?
A. I don't know.
Q. Have you heard of a company called FleishmanHilliard?
A. That's a vaguely familiar name, but I

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don't know whether they were ever hired by Purdue Frederick or Purdue Pharma.
Q. Do you recall at some point being notified of a problem with abuse occurring with OxyContin and Purdue Pharma hiring a crisis management firm?
A. Yes.
Q. Do you recall when that crisis management firm was hired?
A. I don't recall precisely, no.
Q. Have you ever read the interview Michael Friedman gave to the crisis management firm?
A. No.
Q. And in addition to all that, you also put out videos. Are you familiar with the "I Got My Life Back" video?
A. I've heard the title; I'm not familiar with it.
Q. Did you ever do any follow-up to find out whether the participants in the "I Got My Life Back" video actually got their life back or wound up having problems with dependency on OxyContin?
A. No, I did not.
Q. Did Purdue also give away coupons so people could get a week's free supply of OxyContin?

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A. I don't know, but that would be common in the industry.
Q. And all of the things we've just discussed would be done, these marketing efforts, to sell more OxyContin, correct?
A. To see to it that appropriate patients had access to OxyContin, yes.
Q. Were you aware that there was a direct link between the number of sales representatives that were out promoting OxyContin and how much OxyContin would be prescribed?
A. Could you just ask that again?
Q. Yeah. Was there a link -- a direct link between the number of sales representatives that were out promoting OxyContin and how much OxyContin would be prescribed?
A. I don't think "direct link" would capture the concept. So the answer is no.
Q. Do you believe that the number of sales representatives that promoted OxyContin would increase; the more sales representatives that promoted OxyContin, the more prescriptions would be written?
A. I don't think anybody thought of it that way. We had a product that had tremendous potential and our principal means of getting it used

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was to convince physicians -- convince physicians that he had in his practice appropriate patients to use it, but the linkage there is very loose.
Q. Was there also a correlation between the number of times a sales representative called on a physician to how much OxyContin that physician would prescribe?
A. Again, that would be a loose correlation, and there would be -- clearly if he called not at all, there would be nothing to correlate. And I am sure there was a practical limit as to how many calls he could make. I don't know whether there was any kind of specific relationship between calling every quarter or every month or more frequently or less frequently.
Q. Okay. Why don't we mark the OxyContin Launch Plan as 27.
MR. STRAUBER: It's 26.
(DEPOSITION EXHIBIT NO. 26 MARKED)
MR. THOMPSON: And this is going to be 27.
(DEPOSITION EXHIBIT NO. 27 MARKED)
MR. STRAUBER: Mr. Thompson, I note on Exhibit 27 there's some material that's been -- a good deal of material that's been bracketed, and I've seen

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that on other documents that you've marked. My assumption throughout is that the brackets were not on the original and this is something that you guys added.

MR. ELLIS: That is incorrect. The brackets were produced that way.

MR. STRAUBER: It came to you with the brackets?

MR. ELLIS: These documents that have writing on them were produced that way. If the e-mail ends and it's only half an e-mail, that's also the way that they were produced to us.

MR. STRAUBER: And what if the document was highlighted in yellow, was it produced to you --

MR. ELLIS: If it was highlighted in the context that I just gave it to him, I would have added that highlighting just now; but in terms of attachments that aren't connected to the e-mails, that's because we didn't get them from Purdue.

MR. STRAUBER: I'm asking about the --

MR. ELLIS: I'm trying to explain to you --

MR. THOMPSON: Tony, it's okay.

Brackets were not added.

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MR. STRAUBER: Okay. Thank you.

BY MR. THOMPSON:

Q. Sackler Exhibit 27. And this is an e-mail from you, "Phase IV OxyContin Team Minutes" dated 10-23-96, and you have a copy of it.

And -- so this would have been after the launch of OxyContin, correct?

A. Yes.

Q. Okay. And it says here, "Michael: The oxymin12 said:"

What was the oxymin12?

A. I don't know.

Q. Reading from it, it says, "Results showed the following: Physicians who attended the dinner programs or the weekend meetings wrote more than double the number of new prescriptions for OxyContin compared to the control group, and this was sustained over the three-month post-meeting evaluation period. Weekend meetings had the greatest impact, increasing new prescriptions for OxyContin by a factor between 2.16 and 2.62. These results will be presented in more detail at a later date.

"This is very encouraging, although I must allow that a proportion of the percentage without the associated absolute numbers is inherently

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meaningless. Was the number of increased prescriptions commercially significant? If so, what would the cost per increased prescription be assuming that the absolute difference persisted? When will a more complete report be available?"

And was that your --

A. You read it correctly.

Q. -- e-mail?

Did you ever get a more complete report?

A. I don't remember.

Q. And then above that it looks like Alfonse (sic) writes back to you. And Alfonse was --

A. Alfonso.

Q. Alfonso was head of marketing?

A. He was head of marketing.

Q. And he says, "Interesting comments from Dr. Richard. I also wonder if there was a bias in the form of representatives increasing calls to the selected physicians. Would we get the same ROI" -- is that return on investment?

A. Yes.

Q. -- "in prescriptions" -- "Would we get the same return on investment in prescriptions as a result of the representatives increasing the call rate

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to the selected group regardless of dinners? I don't have the list, therefore, I don't know if there was a selected preference toward this group in the part of the reps. It's reasonable that these core doctors were already receiving special attention, which would have generated an increase in prescriptions. If this is the case, the cost of the dinners would unnecessarily increase the cost per prescription."

A. Right.

Q. Did you-all ever determine whether the dinners that you were taking the doctors on were helping to sell OxyContin?

A. I don't remember.

MR. THOMPSON: Let's mark this 28.

(DEPOSITION EXHIBIT NO. 28 MARKED)

(Passing document.)

Q. And this says, "6-9-99, Dr. Richard Sackler. Subject: Promotion of OxyContin by Abbott."

And if you would go down to the bottom, it says, "Enclosed for your information is a memorandum from Mark Alfonso that describes a substantial increase in Abbott's field force allocation toward OxyContin. 120 Abbott reps previously selling urokinase, which has been temporarily withdrawn from the market, will be

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assigned full time to OxyContin. This will be totally at Abbott's expense and should have a very positive effect on OxyContin sales."

That is from Michael Friedman, correct?

A. Right.

Q. What was the agreement reached with Abbott to sell OxyContin?

A. I don't recall the details of the agreement.

Q. And then up at the top it says, "Sender: Dr. Richard Sackler." So this would be, I think, your reply to that. And it says, "This sounds very good for the brand. I just hope that we can supply the surge that may follow this program."

And were you referring to a surge of OxyContin sales?

A. Yes.

Q. And was it your expectation that the sales representatives were going to create a surge in OxyContin sales?

A. I didn't know. I said let's hope.

(DEPOSITION EXHIBIT NO. 29 MARKED)

(Passing document.)

Q. And then this is a document that I

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wanted to bring to your attention, because we were talking earlier today where you said -- you know, when I was pointing out to you the documents from your officers that said OxyContin is believed by other physicians to be not as strong as morphine.

Remember us having that discussion?

A. I recall.

Q. And this is a Phase II OxyContin Tablets Team Meeting, June 13th, 1997.

So this would be well over a year after -- a year and a half after OxyContin has been launched and in the marketplace, correct?

A. Yes. About a year and a half. Maybe a little less.

Q. And if you could go to the -- it says "Marketing and Sales Update." The first paragraph. "Mike Cullen discussed in detail marketing's positioning of OxyContin. He explained we want to expand extensively in the non-cancer market segment while promoting OxyContin as the one to start with in cancer pain and the one to stay with through proper titration."

And the next paragraph reads, "We can show that we are as effective as morphine, but do not want to say OxyContin is as powerful as morphine."

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Now, did I read that correctly?

A. You read the words.

Q. "Words such as powerful may make some people think the drug is dangerous and should be reserved for the more severe pain."

MR. STRAUBER: If I could interject for one second. While you are reading it correctly, what you haven't included is the fact that the word "powerful" is in quotes.

MR. THOMPSON: Yes.

MR. STRAUBER: Okay.

MR. THOMPSON: We'll read it again and include those.

Q. "We can" -- second paragraph. "We can show that we are 'effective' as morphine, but do not want to say OxyContin is as 'powerful' as morphine. Words such as 'powerful' may make some people think the drug is dangerous and should be reserved for the more severe pain. This could have a negative effect in the much larger non-cancer pain market. Mike reminded the team that we should keep this positioning in mind as we develop future marketing programs, symposia, clinical study manuscripts and any other items that discuss the use of OxyContin."

Did I read that correctly?

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A. Are you asking me?

Q. Yes.

A. I believe you did.

Q. All right. Were you aware that your marketing and sales team were being careful not to and did not want to say that OxyContin is as powerful as morphine?

A. I don't recall if I was aware of this.

Q. And, in effect, it's twice as powerful as morphine, correct?

A. No, it's not. We've gone through this quite a few times. And here "powerful" is in quotes. Sometimes the words "stronger," "weaker," "powerful" are not in quotes. But here it is very clear that it was specifically the word "powerful" that he did not -- he was advising people to stay away from. It had nothing to do with potency.

Q. When you go in and see a doctor and you say -- if they say OxyContin is not as powerful as morphine, what do you think the doctor thinks?

A. He was not supposed to say that, and I don't think he did say that. That would create confusion. He was warning not to use the word "powerful" in any context. But he clearly didn't mean potency, because potency was declared as twice as

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potent as morphine from day one of marketing to yesterday and today in every piece of material, in all the conversion charts and was recognized and understood by physicians.

THE WITNESS: Do you want to take a break now?

MR. STRAUBER: It's almost 3:30. Would this be a time to take a break?

MR. THOMPSON: This would be a great time.

VIDEOGRAPHER: We are off the record at 3:27 p.m.

(RECESS)

VIDEOGRAPHER: We are back on the record at 3:42 p.m.

BY MR. THOMPSON:

Q. Okay. A while ago when we were talking about salespeople making calls, did I understand you to say that you did not believe the number of calls made by a salesperson affected the number of prescriptions for OxyContin?

A. I didn't mean to communicate that.

Q. Thank you. In fact, Purdue had requirements on their salespeople that they had to make a certain number of calls every day to

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physicians, correct?

A. There was a standard number of calls, yes.

Q. And before we broke, we were discussing this Phase II OxyContin Tablets team meeting. And to kind of put this in perspective, there was this e-mail dated 6-2-97 -- so that's June 2nd, '97 -- that we were discussing earlier where we discussed that physicians did not think OxyContin was as strong as MS Contin and that perception was out there, and it noted that it was important to be careful not to change the perception by physicians toward Oxycodone when developing promotional pieces.

MR. STRAUBER: Mr. Thompson, if you're referring to another document, could you identify it and give it to the witness?

MR. THOMPSON: We've already talked about it earlier. I'm just asking a question right now.

MR. STRAUBER: Well, but you're asking your question based on the earlier document and reading from the earlier document.

MR. THOMPSON: I won't read from it then.

Q. Let me ask you. Do you recall us having that conversation?

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A. I'm not sure which documents. I've seen a lot of documents. But I do recall having -- talking about this many times, yes.

Q. Yes. And your comment was, Well, we're not saying that it's not as strong, we're saying it's not as effective. I'm sorry. Let me rephrase that.

MR. STRAUBER: I object to the form of that question.

Q. Your comment was, We're not trying to convey that it's not as powerful; is that correct?

A. No. What I thought I communicated -- perhaps I didn't do it well -- was that the meaning of that word "strong" was not that it was a weak drug, weaker than morphine. It was not that meaning. The meaning related to the stigma of morphine and to the fear of morphine. And precisely in this case I believe that the efficacy of the drug -- and I really would like to see the document, if I might, if we're going to talk about it, because I'd like to refresh my memory not only as to the document but as to what I had meant to say if I didn't say it clearly.

Q. Here's the one we were talking about when we broke.

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(Passing document.)

MR. STRAUBER: What exhibit is that, sir? Is that 29?

THE WITNESS: 29.

MR. THOMPSON: It's on the bottom.

THE WITNESS: 29.

MR. STRAUBER: 29. Okay.

Q. And they've actually used two words here that are in quotes, correct? One is "effective" and one is "power." And the sentence reads, "We can show that we are as effective as morphine, but we do not want to say OxyContin is as powerful as morphine." Did I read that correctly?

A. That's correct.

Q. Have you reviewed the "OxyContin Abuse and Diversion and Efforts to Address the Problem" that was put out in December of 2003 by the GAO?

A. No, I did not review that.

Q. I'll give you a copy of that.

(Passing document.)

You've never seen that document; is that correct?

A. Do you want to mark it as an exhibit?

Q. I will, yes. But have you ever seen that document?

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A. I don't recollect seeing that document.

Q. If you would, turn to page 9. And I'm looking at the second paragraph, last two sentences. "In both 2001 and 2002, OxyContin's sales exceeded 1 billion and prescriptions were over 7 million. The drug became Purdue's main product, accounting for 90 percent of the company's total prescription sales by 2001."

Is that information correct?

A. To the best of my recollection, it's correct -- very close to correct.

Q. And if you'll turn to page 17. Under the heading "Purdue Focused on Promoting OxyContin for Treatment of Non-Cancer Pain," and if you go down to the last sentence in the second paragraph, it says, "One of Purdue's goals was to identify primary care physicians who would expand the company's OxyContin prescribing base. Sales representatives were also directed to call on oncology nurses, consultant pharmacists, hospices, hospitals and nursing homes."

Is that information accurate?

A. As a general proposition, yes. It doesn't include oncologists. I don't think -- in the spirit I think it's accurate.

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Q. And then down, the second sentence from the bottom, "Purdue has stated that by 2003 primary care physicians had grown to constitute nearly half of all OxyContin prescribers, based on data from IMS Health, an information service providing pharmaceutical market research."

Is that information accurate?

A. I can't vouch for the accuracy of this.

Q. The next sentence says, "DEA's analysis of physicians prescribing OxyContin found that the scope of medical specialties was wider for OxyContin than five other controlled-release, schedule II narcotic analgesics. DEA" -- and is that the Drug Enforcement Agency?

A. I believe it would be.

Q. "DEA expressed concern that this related in OxyContins being promoted to physicians who were not adequately trained in pain management."

Do you recall the DEA expressing that concern?

A. No.

Q. The next two sentences. "Purdue's promotion of OxyContin for the treatment of non-cancer pain contributed to a greater increase in

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prescriptions for non-cancer pain than for cancer pain in 1997 through 2002. According to IMS Health data, the annual number of OxyContin prescriptions for non-cancer pain increased nearly tenfold, from about 670,000 in 1997 to 6.2 million in 2002."

Is that information accurate?

A. I don't know. I just don't have these numbers in my mind.

Q. If you'd go to page 20, the second paragraph. "By more than doubling its total sales representatives, Purdue significantly increased the number of physicians to whom it was promoting OxyContin. Each Purdue sales representative had specific sales territory and is responsible for developing a list of about 105 to 140 physicians to call on who already prescribe opioids or who are candidates for prescribing opioids.

"In 1996, the 300-plus Purdue sales representatives had a total physician call list of 33,400 to 44,500. By 2000, the nearly 700 representatives had a total call list of approximately 70,500 to 94,000 physicians. Each Purdue sales representative is expected to make 35 physician calls per week and typically calls on each physician every three to four weeks. Each hospital sales

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representative is expected to make about 50 calls per week and typically calls on each facility every four weeks."

Was that, to your knowledge, accurate information about how Purdue was marketing OxyContin through its sales force?

A. Without quibbling, it isn't really -- you're asking me to vouch for the accuracy of this. I just don't carry these numbers in my mind, so I can't agree or dis- -- I just don't know. But this is a count of physicians and a description of the standards of calls, but I don't -- but that's -- that really doesn't describe how we were marketing it, to use your question. So I'm not trying to quibble with you, sir, but I just don't know.

Q. All right. And if you'll go down to the middle of that next paragraph. "The total amount of -- the amount of total bonuses that Purdue estimated were tied to OxyContin sales increased significantly from about 1 million in 1996, when OxyContin was first marketed, to about 40 million in 2001."

Do you recall -- do you have any reason to disagree with the 40 million number for bonuses paid out to your marketing salesmen in 2001?

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A. I don't have -- I don't know the number, so I don't have any reason to disagree.

Q. And then if you go to the next page, the last paragraph, it says, "According to DEA's analysis of IMS Health data, Purdue spent approximately 6 to 12 times more on promotional efforts during OxyContin's first six years on the market than it had spent for its older product, MS Contin, during its first six years or than had been spent by Janssen Pharmaceutical for one of OxyContin's drug competitors, Duragesic."

Do you see that?

A. Yes. Yes, I did.

Q. Is that accurate?

A. I don't know. I have no reason to agree with it or disagree with it at this point.

Q. Do you believe Purdue's marketing was overly aggressive?

A. No.

Q. Do you believe Purdue's marketing was appropriate?

A. I believe so.

Q. It says here under -- on page 30, "OxyContin's Wide Availability May Have Increased Opportunities for Illicit Use."

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A. I'm sorry. What page are you reading from?

Q. Page 30.

A. Page 30?

Q. Yes.

A. 3-0. Okay. Where should I look?

Q. Last paragraph.

A. Okay. Thank you.

Q. "The large amount of OxyContin available in the marketplace may have increased opportunities for abuse and diversion. Both DEA and Purdue have stated that an increase in a drug's availability in the marketplace may be a factor that attracts interest by those who abuse and divert drugs."

"OxyContin" -- if you go on down. "OxyContin became the top-telling name-brand narcotic pain reliever seller in 2001..."

Is that accurate?

A. I don't know, but -- I just don't know.

MR. THOMPSON: So let's mark that as Exhibit 30.

(DEPOSITION EXHIBIT NO. 30 MARKED)

Q. Have you ever seen an article called

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"What Happened to the Poster Children of OxyContin"?

A. No, that doesn't sound familiar.

Q. Nobody has ever provided that to you at Purdue Pharma?

A. When was it published?

Q. September 8th, 2012.

A. No. That wouldn't necessarily have been provided to the board. But I don't -- I really -- I'm not familiar with it.

Q. Do you recall a time when Purdue's OxyContin was considered so successful that other companies were thinking about whether they could make their own version of OxyContin?

A. Just -- just -- ask the question again so I can answer it.

Q. Sure. Do you recall a period of time where OxyContin was considered so successful that other companies were considering making their own version of OxyContin?

A. I can't say that they did it because it was, quote, so successful, but I do recall that I did hear that other companies were trying to copy OxyContin, yes.

(Passing document.)

Q. So this is an e-mail chain that was

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provided. Let's go ahead and mark that as 31.

(DEPOSITION EXHIBIT NO. 31 MARKED)

Q. And if you go to page 2 it says, "Subject: Press release or similar promotion. Author: Dr. Richard Sackler, 8-23-96."

A. Just let me catch up with you. 8-23 -- oh, the bottom of the page. Okay, I'm with you.

Q. And it says, "I think it is noteworthy to release information on OxyContin Tablets, its use and success in the market and the tremendous reception it received in Vancouver." Basically, "The newsworthy occasion is that this product has achieved our first year's sales projection four months early and that by the end of the year we should have 130,000 to 150,000 per salesman of sales.

"The objectives of this release would be: Stimulate interest in the U.S. community -- in the medical community of the U.S. to recognize the tremendous success of OxyContin Tablets clinically and the ratification commercially. We want many more physicians than have presently used it to become aware of its availability and importance in their practice. It would be hoped that this would lead to greater use by those currently prescribing and broaden our

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prescribing base in the U.S. and Canada."

Do you know whether that press release took place?

A. I don't know.

Q. And then above that it looks like there's a response to your e-mail from Robert Reder.

A. Yes.

Q. "Given the diverse in both short- and mid-term goals, I would recommend a full-fledged PR firm with a one- to three-year contract. That way this can be coordinated actively to achieve all goals rather than a one-shot flash. Is this a departure from traditional PF/PPLP?"

And that's Purdue Frederick/Purdue Pharma, L.P. strategy; is that correct?

A. Correct.

Q. And you wrote back and said, "I don't see this as a 'departure' from policy."

And then it looks like -- and perhaps this is Friedman who says, "My view is different. If you want to use PR to signal our market as to our development pipeline, I have no problem. I do not want to spend money on PR to increase sales. We do not need to have an agency in our pockets. I have learned my lessons."

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And then you write back on page 1 and say, "I agree about the agency. I want to signal the licensing in market for the product around the world, get an audience for our patent infringement suits so that we are feared as a tiger with claws, teeth and balls and build some excitement with prescribers that OxyContin Tablets is the way to go."

And what was your concern there about licensing and patent infringement?

A. Well, licensing in market meant the -- get the attention of companies that had products that might be attractive for us to license.

Q. Do you recall Howard Udell making a trip down to Kentucky to meet with Attorney General Greg Stumbo and other members of the -- of his staff?

A. I don't recall it, no.

Q. This is a letter dated May 17th, 2005. And that would be prior to the felony plea agreement that Purdue Frederick entered into, correct?

A. I'm not -- I think I'm clear on the dates and that that would be correct. Please correct -- somebody here correct me if I'm wrong.

(Passing document.)

Q. If you'll turn to page 6. This appears to be a letter from Howard Udell dated May

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17th, 2005 to Greg Stumbo, the Attorney General of Kentucky. And he points out that none of the federal courts in Kentucky has found any misconduct on the part of Purdue. Correct?

A. I'm not sure just where you're reading from.

Q. Oh, I'm sorry. I'm on page 5.

A. Oh, page 5. I'm sorry. I was on the wrong page. And where are you reading from?

Q. The third paragraph down.

A. It begins, "I believe that even this brief..."?

Q. No. I'm reading in the middle of the paragraph. "Significantly, however, not one of these courts has found any misconduct on the part of Purdue."

A. Please bear with me while I try to find this.

Q. Do you see that? Right above the case cites.

A. I'm sorry. In the paragraph that has a list of cases?

Q. Yes. The paragraph right above it.

A. "Significantly, however..." Thank you.

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Q. Yeah. Purdue answered -- filed an answer in all of these cases and claimed they had never done anything improper or wrong; isn't that true?

A. I don't know.

Q. Are you aware prior to the --

A. That is, I don't know whether we filed in all these cases or whatever. That's what I mean when I say "I don't know."

Q. Are you aware of Purdue ever admitting to doing anything improper prior to the plea agreement where the company pled guilty to a felony of misbranding a drug with the intent to defraud or mislead?

A. Okay. Just ask the question. Before the plea am I what? Aware?

Q. Are you aware of anyone at Purdue ever admitting they did anything improper prior to entering into the plea agreement where the company pled guilty to misbranding a drug with the intent to defraud or mislead?

A. I am not aware of anybody.

Q. And then if you go to page 6, the middle of the second paragraph from the bottom, it says, "First, any suit brought under the Act requires

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proof that a defendant engaged in a practice of violation of KRS 367.170, an unsurmountable obstacle since Purdue has committed no unlawful act."

Did I read that correctly?

A. You did.

Q. And were you aware that Howard Udell had communicated with Greg Stumbo that Purdue had committed no unlawful act on May 17th, 2005?

A. I think he was writing for Purdue Pharma, just for clarity, but I was not aware of this.

Q. And May 17th of 2005, did Purdue Frederick exist?

A. I don't know.

Q. Do you know if the companies were merged at some point?

A. I don't believe they were.

Q. Let's talk about the Agreed Statement of Facts.

MR. ELLIS: Might as well mark both the letter and the Agreed Statement of Facts.

MR. THOMPSON: Yeah, that's a good idea, T.

MR. ELLIS: The letter is going to be Exhibit --

MR. THOMPSON: 32.

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MR. ELLIS: -- 32, and the Agreed Statement of Facts is going to be Exhibit 33.

(DEPOSITION EXHIBIT NOS. 32 AND 33 MARKED)

MR. STRAUBER: By "the letter," you're talking about the Udell letter?

MR. ELLIS: Yeah, May 2005.

Q. Who was in charge of preparing and approving the sales and marketing materials at the time of OxyContin's release?

A. I'm sorry. At the time of OxyContin's --

Q. Release?

A. Release, meaning launch?

Q. Launch.

A. Michael Friedman, I believe.

Q. And at that time -- at the time of the launch, who was in charge of the marketing department?

A. To the best of my recollection, Mark Alfonso.

Q. And Michael Friedman, was he the person who ultimately was appointed CEO of Purdue?

A. He was. Purdue Pharma.

Q. Is he one of the individuals who pled guilty to the misdemeanor at the time of the plea

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agreement?

A. Yes.

Q. Do you recall whether Purdue had received warning letters about its marketing of MS Contin?

A. I don't recall.

Q. You don't recall six warning letters coming in from MS Contin?

A. No, I don't -- I don't recall the instances.

Q. Do you recall Purdue getting warning letters with respect to the way it was marketing MS -- marketing OxyContin?

A. I don't recall.

Q. Do you know if Purdue consistently denied it was doing anything wrong with respect to marketing OxyContin?

A. I'm not sure. I would think that we denied doing anything wrong, but that's a guess on my part. I don't really know.

Q. The guilty --

A. I don't recollect.

Q. Were you involved in approving the Agreed Statement of Facts for the guilty plea?

A. The board voted in favor of

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management's recommendation that we have -- that we plead guilty under a plea agreement with the U.S. Attorney.

Q. And just so there's no confusion, the board voted to adopt the Agreed Statement of Facts; is that correct?

A. I don't know. I don't remember.

Q. Is the Agreed Statement of Facts accurate?

A. I believe it is.

Q. And in addition to the guilty plea of a felony for misbranding a drug with the intent to defraud or mislead -- and that drug is OxyContin, correct?

A. I believe it is.

Q. -- these three individuals, Howard Udell, Michael Friedman and Paul Goldenheim, also pled guilty to misdemeanors, correct?

A. Yes.

Q. And Howard Udell was Purdue's executive vice president and chief legal officer?

A. He was.

Q. Michael Friedman was the president and CEO of Purdue at the time of the guilty plea?

A. I believe he was.

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Q. And Paul Goldenheim was the former executive vice president for worldwide research and development and chief scientific officer, correct?

A. I believe so.

Q. By 2006 Dr. Goldenheim had already left Purdue, correct?

A. Yes.

Q. Did he leave voluntarily?

A. He did.

Q. What reason did he provide you regarding why he was leaving Purdue?

A. He was leaving Purdue in order to be CEO of another company.

Q. Have you seen this Agreed Statement of Facts before?

A. Before today? Yes.

Q. Did you provide comments on this document?

A. No, I did not.

Q. Were you surprised by any of the allegations in the document?

A. I don't -- I didn't read the whole document, so I can't say if there are allegations that would surprise me. I had understood that this was a settlement document and that people in the company who

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investigated thoroughly said to the board that the statements in the document were true.

Q. And when you say "I didn't read the document," as we sit here today, have you ever read the entire document?

A. No.

Q. At the time this was signed, May 7th and 8th of 2007, what was your position in the company?

A. I was a director of the company.

Q. Did you have any other role at that time?

A. Not to my recollection. For a period of time after I ceased to be CEO in early 2003, I was co-nonexecutive chairman of the board. But that came to an end more or less around this time, but I don't remember whether it was before the plea or after.

Q. You ceased to be CEO in 2003; is that correct?

A. That's correct.

Q. When were you first notified that the U.S. attorneys for the Western District of Virginia were investigating Purdue?

A. I can't recall precisely. We were, as a board, notified that the U.S. attorney was

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investigating OxyContin abuse and diversion and that the law department in general and Howard Udell in particular were providing any documents he wished voluntarily to help his investigation. That the investigation turned on Purdue was a surprise, but I don't remember when that happened.

Q. Was it before you left as CEO?

A. I don't recall.

Q. Do you recall there being issues about addiction, dependency, tolerance buildup, abuse and diversion prior to your leaving as CEO?

A. Yes. Not all of those, but abuse and diversion, yes.

Q. Do you recall there being issues with addiction?

A. Yes. Same time as I was informed about possible abuse and diversion.

Q. And when were you first informed about possible abuse and diversion?

A. Sometime in 2000 an article was published in a newspaper in Maine that very graphically described the impact of abuse and diversion of individuals who were using OxyContin. That was the first -- the first time I became aware of that possibility.

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Q. Do you recall receiving a letter or being notified about a letter from a hospital in Pikeville or Hazard concerning problems with patients who were on OxyContin?

A. I don't recall a letter. Was it directed to me?

Q. I don't believe so. I think it came to Purdue, and I'm wondering if you saw it.

All right. Let's go back to the plea agreement and we'll try to get through this.

Are you aware that we've requested Purdue to identify the names of documents referenced in the Agreed Statement of Facts?

A. I'm not aware of that.

Q. Are you aware we've asked them to identify the individuals who are referenced in the Agreed Statement of Facts?

A. No.

Q. Paragraph -- if we can go to paragraph 13 of the Agreed Statement of Facts. Paragraph 13 says that on December 28th, 2004 "Purdue submitted an OxyContin NDA to the FDA. The NDA included clinical trials showing that OxyContin, when dosed every 12 hour, was as safe and as effective as Immediate-Release Oxycodone dosed every 12 hours."

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A. Every six hours.
Q. I'm sorry, every six hours, yes.
A. Yes, that's what it says.
Q. And then paragraph 14 says, "The NDA did not claim that OxyContin was safer or more effective than Immediate-Release Oxycodone or other pain medications, and Purdue did not have and did not provide the FDA with any clinical studies demonstrating that OxyContin was less addictive, less subject to abuse and diversion or less likely to cause tolerance and withdrawal than other pain medications."
Is that paragraph correct?
A. That's what it says. I don't know if it's correct, but I wouldn't differ with it.
Q. And then there are some medical officer reviews, correct?
A. Yes. I believe those are within the FDA.
Q. Right. And those also did not state that OxyContin was more effective than or superior to, safer, had less opioid effects or caused fewer adverse events than any other marketed product, correct?
A. I believe that's true.
Q. And let me back up a minute.
Do you know what -- when salespeople

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go call on physicians what type of information the physician usually asks the salesperson?
A. I would not be able to comment on that.
Q. You don't know whether they want to know if there's any studies, if there's any contraindications to the medicine, any problems reported? Have you ever heard that sort of thing?
A. That makes sense. I thought you meant in more -- that's a very general thing. They want to understand what is the medicine for, what kind of condition, who are the patients, what is the -- what is the effectiveness. They might ask for comparative effectiveness if it exists; and if it doesn't exist, the answer is we can't give you any. They might ask about safety. They might ask about anything related to what they feel they should know when they -- were they to use the medicine.
Q. One of the things they might ask is why is it better than what I'm already using, why should I switch. Is that reasonable?
A. Perfectly reasonable.
Q. One of the things they might ask is, you know, you got any studies that show it's better. Is that another thing that comes up?

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A. They might.
Q. Paragraph 16 says, "The Medical Officer Review of the ISS included these statements: The blood level data in clinical use suggests the opioid effects of OxyContin and Immediate-Release Oxycodone would be similar."
To your knowledge, is that clinically correct?
A. Well, it's an inference, and I certainly can't differ with the inference. But it may not be correct.
Q. Under "d" it said, "Withdrawal is possible in patients who have their dosage abruptly reduced or discontinued."
Is that your understanding of the characteristic of the drug?
A. Absolutely.
Q. Then it said, "Care should be taken to limit competitive promotion. OxyContin has been shown to be as good as current therapy, but has not been shown to have a significant advantage beyond reduction in frequency of dosing."
Is that your understanding of the characteristic of the drug?
A. No. It is my understanding that that

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statement is correct. But the reason I said that that may not be the case was the very surprisingly large number of reports from the field that I heard second and third hand, that early in the life of the product doctors spontaneously volunteered that the drug was better than we said it was. And this was so frequent and so unusual that it raised in my mind, and continues to raise, the question maybe it is actually superior, but we were never able to demonstrate using the methods that would be generally accepted that this was the case. It was an impression that doctors developed on their own.
Q. Any studies -- retrospective studies, anything of that nature that would support that statement?
A. No. I said we could never prove it.
Q. So if you go on here under the heading "Misbranding of OxyContin" and -- and when we talk about misbranding, that's just really making claims and statements that aren't true about a drug. That's called misbranding the drug. Is that correct?
A. No, I wouldn't say it's that. I would say it's got a different meaning in the regulatory world. It's stating things that are not strictly in the package insert.

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Q. Okay.
A. They may be true, but if they're not in the package insert, they're misbranding.
Q. Do you know if Purdue had information that physicians were concerned about the abuse potential for OxyContin?
A. I did not have that. It wouldn't surprise me that physicians would be concerned about that as with any other strong opioid or, in fact, any other opioid.
Q. Let me refer you to paragraph 20. It says here, "Beginning on or about December 12, 1995 and continuing on or about June 30th, 2001..."
And that is the time frame that the U.S. Attorney's Office looked into the conduct at Purdue, correct?
A. I don't know.
Q. "...certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications as follows:"
Under "a" it says that you "Trained Purdue sales representatives" -- meaning -- when I say

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"you," I mean Purdue, the company -- "Trained Purdue sales representatives and told some healthcare providers that it was more difficult to extract the Oxycodone from an OxyContin tablet for the purpose of intravenous abuse, although Purdue's own study showed that a drug abuser could extract approximately 68 percent of the Oxycodone from a single 10 milligram OxyContin tablet by crushing the tablet, stirring it in water and drawing the solution through cotton into a syringe."
Were you aware that Purdue trained sales representatives to make that misrepresentation?
A. No.
Q. Is that a misrepresentation that would cause a physician to be more likely to use -- to write prescriptions for OxyContin or less likely to write prescriptions for OxyContin?
A. I would -- I couldn't guess. The implication is that it would be more likely, but I don't know.
Q. And then number "b" says, "Told Purdue sales representatives they could tell healthcare providers that OxyContin potentially creates less chance for addiction than immediate-release opioids."
Were you aware that Purdue told sales

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representatives they could tell healthcare providers that there was less chance for addiction with OxyContin than with immediate-release opioids?
A. No, I was not aware of that.
Q. And under "c" it says, "Sponsored training that taught Purdue's sales supervisors that OxyContin had fewer 'peak and trough' blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids."
Were you aware that they were teaching sales supervisors to make that misleading --
A. Absolutely not.
Q. -- statement?
Under "d" it says, "Told healthcare providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug."
MR. STRAUBER: I object to the form of the question. In reading "d," you omitted the word "certain" which appears before "healthcare providers."
Q. Oh. Well, let me read it again.
Under "d," "Purdue told certain healthcare providers that patients could stop therapy

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abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug."
Were you aware that certain healthcare providers were being told that they could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug?
A. No.
Q. Okay. And that statement is false, correct?
A. It -- no. It's -- it's not clear to me it's false, but I am eager not to contend with it. It says "certain healthcare providers" and it -- the rest of it is conditioned really, in large measure, on, in the first case, the dose that the patient is on, and the second case in the duration that the patient is on. But reading between the lines, as I suspect those who shaped this did and understood the government, I can accept it as being a reasonable expression of improper conduct. That is, certain healthcare providers might have been told regardless of dose or regardless of duration.
But had I known about this, I would have alerted our attorneys when negotiating this that

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this ought to be a little bit more specific because it's going to be difficult to agree with it the way it's written. But I'm -- I won't quibble with it.

Q. Well, there was actually a whole lot of back and forth on this document.

A. There may have been, but it wasn't with me.

Q. And a lot of the things brought up the U.S. Attorney's Office said, no, we've reviewed the documents and we're not changing this stuff.

Is that what happened?

A. I don't know.

MR. STRAUBER: Just to be clear, in the document we're reading, the Agreed Statement of Facts, "Purdue" refers to the Purdue Frederick Company, which is the practice we've had in this deposition from the outset that you've used "Purdue" to refer to Purdue Frederick.

Q. Yes. And because nobody at Purdue is able to say which employees were Purdue Frederick and which employees were Purdue Pharma as far as I've been able to ascertain in any of the depositions I've read so far, and including ones taken in the past, but we'll cover that later.

Under "e" here it says that Purdue --

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"Certain Purdue supervisors and employees, with the intent to defraud or mislead, told certain healthcare providers that OxyContin did not cause a 'buzz' or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could not be -- and could be used to 'weed out' addicts and drug seekers."

Were you aware that those statements were being made to healthcare providers?

A. No.

Q. And then the next section is "Misbranding of OxyContin: Use of Graphical Depictions by Sales Representatives." And it says, "Data from Purdue's clinical studies was used to create the following graphical demonstration of the difference in the plasma levels at steady state between patients who took OxyContin every 12 hours and patients who took Immediate-Release OxyContin every 6 hours."

And it says that "On October 12th, 1995, Purdue requested comments from the FDA's Division of Drug Marketing, Advertising and Communication about its proposed launch marketing materials, which included the following graph and text

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showing Oxycodone plasma concentration provided by OxyContin on a logarithmic scale along with a statement that OxyContin's Oxycodone blood plasma levels provided fewer 'peaks and valleys' than Immediate-Release OxyContin."

MR. STRAUBER: Oxycodone.

A. Oxycodone.

Q. Oxycodone. I'm sorry.

Paragraph 23 says, On December 20th of '95, after --

A. We're going -- I'm sorry. Turn the page?

Q. Yes.

A. Thank you.

Q. On December 20th, '95, "After reviewing the proposed OxyContin launch materials, DDMAC" -- what is DDMAC?

A. DDMAC. It's the division of the FDA -- I don't know what the letters stand for, but it is the division of the FDA that reviews promotional materials and comments on their agreement that they are reasonably reasonable and accurate and consistent with the package insert or they differ with them and recommend changes or elimination of things.

Q. And to sort of cut through it, what

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they did is they said, if you wish to compare blood levels in this text, we suggest that the blood levels for both dosage forms be presented in the graphic so that the reader can accurately interpret this claim.

They thought it was misleading the way it was, correct?

A. No, I don't -- I don't think so. I think they had a suggestion that we should add that. And I don't know why it wasn't there. We certainly had the data as is shown above.

Q. Okay.

A. So I assume we added the data.

Q. And then it says, paragraph 24, "On or about January 11, 1996, Purdue told DDMAC that it had 'deleted' the statement 'fewer peaks and valleys than with Immediate-Release Oxycodone.'"

They took the statement out, correct?

A. That's what it says. I don't know why. It was true. But I have no knowledge of the dialogue between them or why they took it out.

Q. Did you review any of the studies that were done -- I mean actually get down and look at the data in the studies that were done prior to the launch?

A. I looked at the analysis of studies,

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but I didn't look at the data, that is, the individual case report forms.

Q. And as we sit here today, have you ever seen the data of the studies themselves?

A. No. That would be voluminous, and I don't -- I don't think it would be necessary for a senior executive to do that because every study is subject to extremely rigorous validation of the database with the paper record, the paper record that exists with the doctor's own records.

And so this approach, which has been standard in the industry and, I believe, part of good laboratory practices or one of the other standards that the FDA has promulgated, is extremely exhaustive, which is one of the reasons the studies take so long, because the validation of the data can take anything from a month to a year.

Q. Are you saying that your studies that you did before putting Purdue on the market were extremely exhaustive?

A. They were certainly appropriate for a molecule that had been in use, at that point, 80 years or more, that was believed then to be safe and effective as a molecule, and that had no -- at that time no long-term toxicities that hadn't been

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well-developed, and so a lot of that information was brought into the package insert whether we observed them in the trials or not.

So the standards for this kind of an approval, which has its own designation, are easier to meet. They're called 505(b)(2) NDA, and draw upon, in this case, a vast public literature, as I said extended back 80-plus years. So for that it was very extensive in those kind of applications.

Q. But when you took a controversial opioid and expanded it to non-malignant pain at pills that contained high dosages of opiate, you didn't do any addiction studies before putting it on the market, correct?

MR. STRAUBER: I object to the form of the question.

A. First of all, the compound Oxycodone was mostly used in non-malignant pain before we entered the market. That was where the market -- the great bulk of the market existed. So there was no innovation or change in our bringing it to the non-malignant pain market.

The second thing was that we didn't -- we assumed that it was potentially addictive, that it could be subject to abuse and diversion, and the

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package insert then and through many changes has not denied that, in fact, has called it out explicitly in several places, including right in the front of the label when we said it was a Class II narcotic, and every doctor knows that Class II narcotics are among the most abusable products.

Q. A Class II narcotic that your own records show there was a belief among physicians that it wasn't as strong as morphine, correct?

A. No. That it wasn't stigmatized as morphine was. They knew it was -- if you would ask them, Is it more potent than morphine, many physicians knew it was more potent. If they used both drugs, they knew that they would always start with a much lower dose of Oxycodone than they would with morphine.

Q. So you think physicians -- most physicians knew it was more potent than morphine?

A. Yes. They also knew what doses to use it in.

MR. THOMPSON: Let's mark this as Exhibit --

MR. STRAUBER: It's 34.

(DEPOSITION EXHIBIT NO. 34 MARKED)

(Passing document.)

Q. Let me refer you to the first

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paragraph of this document dated January 26th, 2001.

We're now five years after OxyContin has been on the market, correct?

A. Which part of this should I read from? Yes, the date is around five years from marketing.

Q. And it says up here -- this is from Mark Alfonso. The first paragraph says, "I think it will. In the mind of the physicians, hydrocodone gives them a great degree of comfort. Physicians rank the drugs based on the position that they have created in their mind as a result of prescription" --

A. Prescribing.

Q. -- "prescribing habit and promotion." And promotion would be, what, marketing from Purdue Pharma?

A. No.

Q. What do you think it means when it says --

A. Promotion is the promotion of everybody in the industry from going back years and years.

Q. Okay. It says, "For them morphine and hydromorphone are the most potent, followed by Oxycodone and then hydrocodone."

A. I see it.

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Q. Yeah. Were you aware that on January 25th of 2001 Mark Alfonso -- and what was his role at Purdue?

A. He was head of marketing.

Q. -- the head of marketing, felt like physicians did not feel like Oxycodone was as potent as morphine?

A. We've gone through this before. It was -- that was a term that didn't refer to relative potency, it just didn't. He didn't include Fentanyl in this, which is the most potent, but is often used before hydrocodone or morphine.

Q. Well, let me ask you this --

A. So -- well, I'm just saying, it just -- I realize that you've changed the meaning that was intended and understood by the recipients.

Q. No. That's his word, "potent," not mine, correct?

A. No, no, no. You've changed the meaning of the word "potent." Not the word, the meaning of the word.

Q. Well, I didn't change it. It's -- it's his word.

A. No. You've changed it when you've tried to use it as though it means relative potency.

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Q. All right. When we first discussed the first group of documents, you said, no, they're just talking about effectiveness, not strength. The second group of documents where they said it's stronger than morphine, you said, no, they just mean strong in a general sense, they don't mean potent. Here they use the word "potent."

Do you just not think physicians don't think it's as strong as morphine? Because that's what they keep saying they don't want to clear up in the physicians' mind, that it's as strong as morphine.

A. It -- this is a hierarchy here.

Q. Okay.

A. Okay?

Q. Well, we'll just have to disagree about that.

A. Here Mark Alfonso said here that -- if following your reasoning, if your reasoning were correct -- the physicians would see morphine as the most potent of all these drugs. It was the for them morphine, and then hydrocodone, and in most places Oxycodone, and then hydrocodone.

The facts are that hydromorphone is three to eight times more potent than morphine, but that isn't how he listed it. And hydrocodone and

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Oxycodone are close to equal potent. But he didn't say "potent," he said "powerful," and "powerful" in this case has to do with the hierarchy that they place drugs. Morphine was the last because it was the most stigmatized.

Q. So when he says here, "Remember that we tried to reposition OxyContin as powerful as morphine and we could not, finally we decided not to mess with this perception since it was helping us in the non-cancer market."

Did you see where he wrote that?

A. I see where he wrote it.

Q. All right. Let's go back to the plea agreement.

MR. ELLIS: Tyler, we need to mark that document.

MR. THOMPSON: It's marked.

MR. STRAUBER: It's No. 34.

Q. Paragraph 25 of the Agreed Statement of Facts says, "On or about December 1998, Purdue sponsored training for all its district sales managers."

Now, it wasn't some of them, it's all of them, correct?

A. It says "all."

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Q. "During this meeting, a pharmacist retained by Purdue" -- do you know who that pharmacist was?

A. No.

Q. -- a pharmacist retained by Purdue to conduct a portion of the training used the following graphical demonstration (instead of the graphical demonstration of the actual clinical data described in paragraph 21 of this Agreed Statement of Facts) and falsely stated that OxyContin had significantly fewer 'peak and trough' blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids." And they've got a graph that was used at the training for the Purdue employees.

A. I would call that a cartoon, not a graph.

Q. And it says on paragraph 26, "Beginning in or around 1999, some of Purdue's new sales representatives" -- those would be Purdue Pharma sales representatives in 1999, correct?

A. I can't say.

MR. STRAUBER: Object to the question.

Purdue is defined in this document as Purdue Frederick.

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MR. THOMPSON: Yeah, but it says "new sales representatives."
Q. So are we talking about Purdue Pharma or Purdue Frederick?
A. I just don't know.
MR. STRAUBER: The document on its face is talking only about Purdue Frederick.
MR. THOMPSON: Yeah. The guy that helped put the document together, the lawyer, we took his deposition. Have you seen his deposition?
MR. STRAUBER: I've seen his deposition.
MR. THOMPSON: Yeah. And he says he doesn't know if they're Purdue Frederick or Purdue when he refers to this.
MR. STRAUBER: I'm telling you, I'm taking this document on its face defines Purdue as Purdue Frederick. I don't care what anyone else said.
MR. THOMPSON: Sure. And I'm asking him if it's correct, and he's saying --
Q. You don't know, correct?
A. That's -- go -- I said I don't know who employed these new representatives.
Q. Okay. It says, "Some of Purdue's new sales representatives were permitted, during training

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at Purdue's training headquarters, to draw their own blood level graphs to falsely represent that OxyContin, unlike immediate-release or short-acting opioids, did not swing up and down between euphoria and pain and resulted in less abuse potential.
Were you aware that the sales reps were doing that?
A. No.
Q. And then it says, "During the period 1999 through June 30th, 2001 Purdue reps used graphical depictions similar to the one described in paragraph 25 of this Agreed Statement of Facts and falsely stated to some healthcare providers that OxyContin had less euphoric effect and less abuse potential than short-acting opioids."
Were you aware that they had --
A. No.
Q. -- engaged in that conduct?
A. No. I'm sorry.
Q. And then to go on with the conduct, paragraph 28 says, "Misbranding of OxyContin: Misleading Use of Article to Claim No Withdrawal or Tolerance," and it proceeds to discuss how Purdue -- well, let's go ahead and read it. I'll try to shorten this a little bit.

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Purdue had an osteoarthritis study --
A. That's okay, you don't have to rush.
Q. Yeah. Are you familiar with that?
A. May I read it? If you don't want to read it into the record, can I just read it and then respond?
Q. Sure. I'll tell you what, it will save time, I'll read it into the record.
A. Okay.
Q. "On or about January 16, 1997, certain Purdue supervisors and employees sent to the FDA the results of a clinical study pertaining to the use of low doses of OxyContin by osteoarthritis patients." They call it the "Osteoarthritis Study." "And a final report that included, in a section pertaining to respite periods, the statement 'No investigator reported 'withdrawal syndrome' as an adverse experience during the respite periods.'
"In a section entitled 'Adverse Experiences by Body System During Respite Periods,' the report summary of the major results listed the most frequently reported adverse experiences in respite periods to be nervousness, insomnia, nausea, pain, anxiety, depression and diarrhea followed by the statement: '28 patients (26 percent) had symptoms

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recorded during one or more respite periods.'"
Did I read that correctly?
A. I think so. I was kind of reading ahead of you.
Q. And then it says, paragraph 29, "On or about May 1997, certain Purdue supervisors and employees stated that while they were well aware of the incorrect view held by many physicians that Oxycodone was weaker than morphine, they did not want to do anything 'to make physicians think that Oxycodone was stronger or equal to morphine' or to 'take any steps in the form of promotional material, symposia, clinical publications, conventions or communications with the field force that would affect the unique position that OxyContin had in many physicians' minds.'"
And did I read that correctly?
A. You read the words correctly.
Q. And was that part of the Agreed Statement of Facts?
A. It is.
Q. And then it goes on to say, "On or about February 12th, 1997, certain supervisors and employees of a United Kingdom company affiliated with Purdue provided certain Purdue supervisors and

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employees with an analysis of the osteoarthritis study together with another clinical study. This analysis included a list of eight patients in the osteoarthritis study and eleven patients in the other study who had symptoms recorded that may possibly have been related to opioid withdrawal, including one patient in the other study who required treatment for withdrawal syndrome."

Did you ever review that study?

A. No.

Q. "The 'Discussion' section of this analysis included the following: 'It's not surprising that some patients in the clinical trials developed some degree of physical dependence and consequently experienced withdrawal symptoms as a result of abrupt discontinuation of OxyContin Tablets. All patients who were suspected to have withdrawal symptoms have been reported, but this may have resulted in a falsely high incidence.

"Of the patients who participated in the osteoarthritis study (in which patients entered respite periods without OxyContin Tablets) many symptoms suspected to be due to opioid withdrawal may simply have resulted from the return of pain. After withdrawal of OxyContin Tablets, patient 6007

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complained of nervousness, patient 2004 complained of insomnia and felt restless, patients 2020 and 2028 were restless and anxious.

"Since these are symptoms which often accompany the return of significant pain, it may be wrong to label these as withdrawal symptoms. Nonetheless, the incidence of withdrawal symptoms in patients treated with OxyContin Tablets is a concern, and it is safer to over report than under report this problem.'

"This analysis' conclusions included the statement: 'As expected, some patients did become physically dependent on OxyContin Tablets, but this is not expected to be a clinical problem so long as abrupt withdrawal of the drug is avoided.'"

Were you aware that certain Purdue employees participating in the final draft of the article regarding the osteoarthritis study that was published in a medical journal on or about March 27th, 2000, were you aware they participated in the publishing of that study?

A. No.

Q. "The 'Results' section of the article" -- I'm reading from paragraph 31.

A. Right.

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Q. -- "included the following three statements pertaining to the incidence of withdrawal syndrome and withdrawal symptoms experienced by study patients: One patient was hospitalized for withdrawal symptoms. The patient who was hospitalized with withdrawal symptoms had completed the study on the previous day and had been receiving CR Oxycodone, 70 milligrams. Symptoms resolved after three days.

"A second patient received 60 milligrams CR Oxycodone, experienced withdrawal symptoms after running out of study medication. The patient had not reported withdrawal symptoms during scheduled respites from doses of 30 or 40.

"Withdrawal symptom was not reported as an adverse event for any patient during scheduled respites. Adverse experiences reported by more than 10 percent of patients during scheduled respites were nervousness (nine patients) and insomnia (eight patients)."

Paragraph 32 says the article included a "Comment" section, summarized the three statements and the "Results" and "further suggested that patients taking low doses could have their OxyContin treatment abruptly discontinued without experiencing withdrawal if their condition so warranted."

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Were you aware they were making that claim?

A. No.

Q. If you go over to paragraph 34, it says, "On or about June 26, 2000, certain Purdue supervisors and employees sent the full text of this osteoarthritis study article..."

Do you know which supervisors and employees sent the full text of this article?

A. No.

Q. Do you know if it was the marketing group?

A. I don't know.

Q. And it says, "...together with a 'marketing tip' to Purdue's entire sales force. The marketing tip stated that a reprint of the osteoarthritis study article was available for use in achieving sales success. The marketing tip also included as one of the articles 12 key points: There were two reports of withdrawal symptoms after patients abruptly stopped taking CR Oxycodone at doses of 60 or 70. Withdrawal syndrome was not reported as an adverse event during scheduled respites, indicating that CR Oxycodone at doses below 60 milligrams can be discontinued without tapering the dose if the patient

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condition so warrants."

It says, "On or about February 13th, 2001, certain Purdue supervisors and employees received a review of the accuracy of the withdrawal data in the osteoarthritis study and stated" --

Now, this is Purdue's own people reviewing this data, correct?

A. That's how I would read it.

Q. And it says, "Upon a review of all comments for the enrolled patients, it was noted that multiple had comments which directly stated or implied that an adverse experience was due to possible withdrawal symptoms. This was followed by a list of 11 study patients who reported adverse experience due to possible withdrawal symptoms during these periods. 106 patients initially participated in the osteoarthritis study. 32 of them withdrew because of severe" -- I'm sorry -- "because of adverse (not necessarily related to withdrawal) and 38 patients remained in the study at 12 months."

And then the next paragraph reads, "On or about March 28th, 2001" -- so this was a month and a half later -- "a Purdue employee e-mailed a Purdue supervisor regarding the review of the withdrawal data described in paragraph 35 of the Agreed Statement of

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Facts asking: 'Do you think the withdrawal data from the osteoarthritis study is worth writing up (an abstract)? Or would this add to the current negative press that should be deferred?' The supervisor responded: 'I would not write it up at this point.' And no abstract was prepared."

Do you see that?

A. I see it.

Q. So am I correct that Purdue was using the marketing material from this article improperly and not reporting the adverse effects and was allowing their sales force to use it?

MR. STRAUBER: I object to the form of the question.

A. Let's break that into one question at a time, please.

Q. Sure. Was Purdue's marketing department using this article?

A. That's what it says here.

Q. And were they using it inappropriately?

A. That's what it says here.

Q. And when somebody pointed out that the withdrawal data from the osteoarthritis study was actually different than how the sales force was using

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it and asked should we write it up or is this going to add to the current negative press and should be deferred, the person's supervisor said, "I would not write it up at this point." Correct?

A. That's what it says.

Q. Do you know if it ever got written up?

A. I don't know.

Q. Do you know if any of these doctors that were shown this were ever told that it actually wasn't correct?

A. I don't know.

Q. Do you know if anybody at Purdue made an effort to go tell these doctors that all of these marketing things that have been brought up in the Agreed Statement of Facts were not correct?

A. I don't know.

Q. Did you yourself ever tell anybody to go inform doctors that these marketing statements that had been used by Purdue's employees that were not accurate were -- were, in fact, not accurate?

A. I was not aware of this story or the study or the marketing materials or statements.

Q. And as the director of Purdue Pharma, you were not made aware of any of this?

MR. STRAUBER: I object to the form of

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the question.

You can answer.

A. I do not recall whether we were -- you're talking about at the time of this document being written?

Q. Yes.

A. I don't recall.

Q. And at the time that this conduct went on, from '96 to 2001, the time period investigated by at least this U.S. attorney under this Agreed Statement of Facts, you were, in fact, the CEO of Purdue Pharma, correct?

A. During 2000, very, very late '99 until early 2003 I was the CEO, yes.

Q. So if this conduct occurred on May 18th, 2000, June 22nd, 2000, February 13th, 2000 and on March 18th, 2001, this employee was told not to write up the withdrawal data because of negative press and that it should be deferred, you would have been the CEO during this time period, correct?

A. Yes.

Q. What was Robert --

A. From '99 until this.

Q. Yeah. What was Robert Reder's role at Purdue?

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A. He was a senior medical officer.
Q. The next paragraph says, "Between June 26, 2000 and June 30th, 2001, Certain Purdue supervisors and employees distributed copies of the reprint of the osteoarthritis study article to all of Purdue's sales representatives for use in the promotion and marketing of OxyContin to healthcare providers, including the distribution of 10,615 copies to certain Purdue sales representatives between February 13th, 2001 and June 30th, 2001."
So it looks like on March 28th the supervisor tells the employee, Don't write up the withdrawal data from the osteoarthritis study, it would add to the current negative press and should be deferred, and between February 13th, 2001 and June 30th, 2001, 10,615 copies of the osteoarthritis study were distributed to sales representatives, correct?
A. That's what it says.
MR. STRAUBER: It says "certain Purdue sales representatives."
Q. Was the purpose of submitting it to the sales representatives so they could show it to the physicians that they called on?
A. I don't know.
Q. There was only 800 sales reps at

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Purdue's highest volume of sales reps during this period of time, correct?
A. To the best of my recollection, that's approximately true.
Q. So if you wanted to give a copy to each sales rep for their own use, you'd probably only need 800; but they printed off 10,615 copies, correct?
A. Distributed, yes.
Q. Is it reasonable to conclude that the sales reps were showing these to the doctors?
A. It's reasonable to conclude that some sales reps may have shown them to doctors, yes. To some doctors.
Q. Do you know if Purdue ever got any of this 10,615 copies of the osteoarthritis article back?
A. I don't know. If this -- when this was found -- and I don't know when this was found -- by sales or marketing management or the medical department, it would have been the practice to recover them, yes. But I don't know if it was found and I don't know if it was done. This all came to light in 2006 or '7, so I don't know. It could have been long past, but I don't know.
Q. It says in paragraph 38, "During the period June 26, 2000 through June 30th, 2001, certain

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Purdue sales representatives distributed the reprint of the osteoarthritis article to some healthcare providers and falsely or misleadingly stated that patients taking OxyContin at doses below 60 milligrams per day can always be discontinued abruptly without withdrawal symptoms and that patients on such doses would not develop tolerance."
And that's not an accurate statement, is it?
A. I don't believe so.
Q. And then with regard to "Misbranding of OxyContin: Use of Reduced Abuse Liability Claims in Marketing," it says, paragraph -- "OxyContin package insert approved by the FDA stated: 'Delayed absorption, as provided by OxyContin Tablets, is believed to reduce the abuse liability of the drug.'"
That's called the Reduced Liability Statement.
"Certain Purdue supervisors and employees instructed Purdue's sales representatives to use this statement to market and promote OxyContin."
Paragraph 40 says, "Certain Purdue sales reps, while promoting and marketing OxyContin, falsely told some healthcare providers that the Reduced Abuse Liability Statement meant that OxyContin

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did not cause a 'buzz' or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to 'weed out' addicts and drug seekers."
It says, "By March 2000, various Purdue supervisors and employees in different parts of the company had received reports of OxyContin abuse and diversion occurring in different communities."
And that "On or about November 27, 2000, certain Purdue supervisors and employees amended the Reduced Abuse Liability Statement to say that 'delayed absorption, as provided by OxyContin Tablets, when used properly for the management of pain, is believed to reduce the abuse liability of the drug,' and instructed Purdue sales reps to use the amended statement to promote and market OxyContin."
Do you know why that statement was changed?
A. I'm not sure -- no, I don't, and I'm not certain where it was changed. In the package insert? I don't know. If it was in the package insert, then that had to be submitted to the FDA to get approval in advance of using it, but I just don't know what this refers to.

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Q. Well, when Purdue found out that OxyContin was being abused and diverted, they changed their packet insert, kind of cleverly really, if you read it right, "When used properly for the management of pain."

Do you know what they meant by that?

A. I don't know what the people who wrote it meant by that or what the FDA understood, because I was not involved in rewriting it.

Q. Okay. The next paragraph says, "From March 2000 through June 30th, 2001, certain Purdue sales representatives, while promoting and marketing OxyContin, falsely told some healthcare providers that the Reduced Abuse Liability Statement and the amended statement meant that OxyContin did not cause a 'buzz' or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and can be used to 'weed out' addicts and drug seekers."

And those statements are not correct?

A. No, they're not correct.

Q. All right.

"Introduction of Misbranded OxyContin Into Interstate Commerce."

And that is actually the guilty plea.

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A. Pardon?

Q. It points out that Purdue manufactured and sold OxyContin in interstate commerce from various locations --

A. Are you reading -- I'm sorry to interrupt you, sir. Just tell me which number I should be following.

Q. It's the very next paragraph.

A. Which is 44?

Q. Yes. And that's just pointing out that Purdue sold OxyContin all over the U.S., correct?

A. Let me read it and I'll tell you if I agree.

MR. STRAUBER: That's not what it says, if you're reading from 44.

MR. THOMPSON: You're right. I'll withdraw the question.

Q. Did Purdue Pharma sell OxyContin all over the U.S.?

A. During what time period?

Q. 1996 to 2001.

A. Yes.

Q. Now, is part of the reason Purdue was able to get away with making these misrepresentations is because Purdue was aware that physicians did not understand the complex processes of treating pain?

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A. I don't think so.

MR. STRAUBER: I object to the form of the question. It's argumentative.

A. Should I answer it?

Q. Sure.

MR. STRAUBER: You can answer it.

A. I don't think so.

Q. Did Purdue's own focus group show that doctors didn't understand whether OxyContin was stronger than morphine?

A. I don't know.

Q. What about the treatment of pain, did you feel like doctors understood or physicians understood prescribing practices that should be utilized for the treatment of pain?

A. You'd have to put a time frame to that or ask the question with more color and more details.

Q. Isn't that the reason you-all were claiming that you needed to spend so much money educating physicians is because they didn't understand pain prescribing?

A. Some physicians learned how to prescribe for pain from materials that we produced or information that sales reps gave them; others knew how

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to treat pain and they would be more interested in trying this agent in comparison to how they were treating pain before.

When we entered the pain market in 1985 in the U.S., there was almost -- it was abysmal in a sense, not ignorance so much as ignoring pain of patients. Doctors just didn't want to deal with it and left patients inadequately treated.

Q. Would you agree that the only way to get a large sales force to use a marketing message is to instruct them explicitly and unmistakably to do so?

A. I don't understand the question.

Q. Mr. Shapiro has testified --

A. Oh, okay.

Q. I want you to assume he's testified that the only way to get a large sales force to use a marketing message is to instruct them explicitly and unmistakably to do so.

Would you agree with that?

A. I really don't understand it.

MR. STRAUBER: Once again, if you're reading from a transcript, please share it with him.

Q. I want you to assume he's testified to that.

A. But I don't --

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MR. STRAUBER: Why should he assume it when you have a transcript in front of you?

MR. THOMPSON: I don't have a transcript in front of me. I'm asking from my own memory.

A. Oh, okay. I don't understand. I don't understand that statement, so I really can't agree or disagree with it.

Q. Do you believe there's evidence of improper training that has occurred at Purdue based upon the Agreed Statement of Facts?

A. I would have to review it. My recollection as you read -- as we read through it was that one or two things involved improper training, but I can't affirm that until I reread it.

Q. Did you ever -- do you know as we sit here today what percentage of your sales force was using these improper statements to educate physicians about prescribing OxyContin?

A. No, I don't know.

Q. Okay. Whether it was a hundred percent, 50 percent, 10 percent; you don't have any idea?

A. I have no idea.

Q. Do you know if anybody at Purdue tried

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to find out how many of their sales force had given physicians improper and incorrect information?

A. I know, as I said before, that from 2000 -- sometime in 2000, as we became convinced that there was a problem, many efforts were launched to train, retrain and to determine whether sales reps were following company policy, and that effort goes on to this day.

We put in place, for example, a whole compliance department in 2003 or 2004 with many employees who reported independently to the board and have continued to report independently to the board to, in a sense, back up the sales department and marketing department's own efforts to assure proper training and compliance with training. But I don't know of any attempt to measure who said what and how many times. When people were properly trained and they deviated from that or went beyond that, they were sanctioned, and many of them were dismissed.

We also had a whole downsizing in the field force from about 2003 or '4 until about 2007 or '8 in which the 800 eventually went down to something like 200. So I don't think there are too many survivors from this period because they were selectively weeded out and because, on average,

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three-quarters of them would have been gone. But I don't -- I can't answer that I know of any attempt to assess blame in that sense or to count.

Q. Yeah. And that's not really my question. My question is, did anybody at Purdue Pharma attempt to go back and find out which reps specifically had made comments to physicians that were improper or misleading about the attributes of OxyContin?

A. The answer is, I don't know.

Q. Would you agree that giving -- making the statements -- the improper statements that are referred to in the Agreed Statement of Facts could compromise patient care?

A. Some of them, yes. In some patients. Obviously not all patients, but in some patients some of the statements could compromise care. I would like to say suboptimize care, but...

Q. And if I understand correctly, you have not reviewed any of the call notes that were pulled by Mr. Shapiro when he was doing his investigation?

A. That's correct. As far as I know. I didn't -- I was shown a few call notes. I didn't ask were these shown to Mr. Shapiro.

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Q. Was there a recommendation made by somebody right about that same time that the call note system be changed?

A. At about what time?

Q. About the same time he was doing his investigation and reviewing the call notes.

A. I believe it was.

Q. Yeah. And do the call notes not contain as much information as they used to back in two thousand --

A. That, I don't know. But the biggest change was to make the first and second-line supervisors audit a substantial percentage of the call notes in their span of control.

Q. If the call notes have less information in them, is it more difficult to audit them?

A. I would have -- I couldn't possibly guess. I don't know what they were before or after. They were very sketchy notes, the ones I saw. I must say, they were selected and shown to me, but the ones I saw were, in some cases, almost indeterminant. You could not know what was happening.

Q. How many did you see?

A. Six, eight. No more. I think

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probably fewer than six or eight, but I'll say six.

Q. And who were those -- who showed those to you?

A. I was shown them during the preparation for the deposition. I had never seen them before.

Q. Were the call notes you were shown call notes from Kentucky reps, or do you know?

A. My recollection is some were.

Q. Did you hire anybody or ask anybody to review Mr. Shapiro's investigation for accuracy?

A. I did not ask would his investigation be audited for accuracy. There were many people in the law department and then the compliance department who may well have done so, but I don't know.

Q. And would you expect if we did our own investigation we would have essentially about the same number of improper call notes that he found?

A. That would be my expectation.

MR. THOMPSON: Do you want to take a little break?

MR. STRAUBER: Let's take a short break.

MR. THOMPSON: That's fine.

VIDEOGRAPHER: We are off the record

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at 5:26 p.m.

(RECESS)

VIDEOGRAPHER: We are back on the record at 5:55 p.m.

BY MR. THOMPSON:

Q. So let me show you an e-mail. If you'll go to page 2 of this e-mail.

(Passing document.)

This is from Jim Speed dated Tuesday, November 30th. Let's mark this as Exhibit 35.

(DEPOSITION EXHIBIT NO. 35 MARKED)

Q. Dated November 30th, 1999. Second paragraph, "During physician calls, this issue is a topic of hot discussion between me and the physician. While many salespeople have sold controlled-release opioids as having less abuse potential, the current situation has placed us in an awkward situation. I feel like we have a credibility issue with our product.

"Many physicians now think OxyContin is obviously the street drug all the drug addicts are seeking. Issues like purposely crushing the 40 milligram and 80 milligrams tabs to 'get high' have been expressed. I have heard from physicians that pharmacists -- and pharmacists that on the streets

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people are finding ways to extract the Oxycodone from the tablet and are using a cotton ball to filter the talc as they draw it up in a syringe for 'main lining.'"

Were you aware that that was a concern in November of 1999?

A. No.

Q. When did you first become aware that OxyContin was being diverted or being abused?

A. In the winter -- to the best of my recollection, winter of 2000. That is early in the year 2000.

Q. Who is Dr. J. David Haddox?

A. Dr. Haddox is both a dentist and an M.D. He's an expert in both analgesic pain -- the use of analgesics and pain management in general, and also, I think, is a recognized expert on addiction and treatment of addiction.

Q. Did he work for Purdue Pharma?

A. He did.

Q. And what about Rena Golden and Windell Fisher, what were their jobs?

A. Rena Golden, I don't know; and Windell Fisher was a sales manager, but I don't recall how high up he was in sales management. He was a -- I

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think he was a regional manager at that point.

Q. And what about Jim Speed?

A. I recognize the name, but I don't -- I can't tell you what his position was. He was a field salesperson. I don't know whether he was a manager or not, if he was a district manager or sales manager.

Q. Is it true that Windell Fisher was a regional manager with oversights for the districts and territories located in Kentucky?

A. I don't know.

Q. Is it true that OxyContin does produce a buzz or euphoria just like -- the controlled-release just like the immediate-release?

A. When used in pain patients --

Q. Yes.

A. -- or when abused?

Q. When used in pain patients.

A. I don't -- I can't tell you the percentages. I'm sure there are some people who might say that they feel a sense of euphoria. I really don't know what "buzz" means when people say they have a buzz; I'm not familiar. But there may be a brief period of time in which they feel some euphoria or sensation.

Q. And whether you feel a buzz or

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euphoria, does that have to do with how quickly the drug works?

A. Not so -- well, that's an element, but it has to do also with the dose, and also with the patient's familiarity. If they've been on the same dose for a while, I would think it's far less likely. And then there's individual patient variation finally.

Q. And with respect to peaks and valleys, do the peaks and valleys that are referred to in all the marketing materials, or a number of the marketing materials, does that have to do with whether somebody experiences a euphoria from taking OxyContin?

A. If they have any psyche -- psychological experience, like euphoria, it's most likely to be at the peak blood level. So the fewer the peaks, the fewer the periods of euphoria. But I'm just generalizing. I'm not telling you that we've ever measured that.

Q. When did you first become aware that Purdue had marketed and promoted OxyContin as having less abuse potential?

A. Not until the investigations were done. And I can't tell you which investigation or when, but I certainly didn't know that people were saying that until I was told by management that they

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had done investigation and found that some people had said that.

Q. Let me -- let me ask you about patients who have not had a prior incidence of addiction or abuse, but just someone who's put on OxyContin and has never had an opioid in the past. Do you know if they're put on a 20 milligram dose of OxyContin twice a day how long they would have to take it before developing dependency?

A. I can give you a guess, but I don't know. It would -- there's enormous individual variation here. So you can't say with any one person or predict that this person will develop dependency or that this person won't at 40 milligrams a day. I assume that's the presumptive daily dose you're asking me about?

Q. Yes. Do you know if Purdue ever conducted any studies to determine how long a non-malignant pain patient who's never had an opioid before would have to be on the drug before they developed dependency or addiction?

A. I'm not aware of those studies being conducted.

Q. Is it fair to say that if Purdue wanted to do a study to make that determination that

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could be done?

A. Dependency, that is, physiologic dependence I think would be an achievable study that could be done. Addiction remains to be seen. A lot of people would say it's almost impossible to do that. But Purdue and other industry partners are just on the -- on the cusp of trying to do that with a number of studies.

Q. Could you do a retrospective study, or could you have done a retrospective study if you had wanted to look at patients?

A. I would have to think about whether I could figure out a retrospective study. It would be an interesting -- it's an interesting question, but I don't know the answer to it.

Q. And what was Robert Reder's role?

A. Robert was a senior medical scientist in the medical department.

Q. And I want you to assume he's testified that Purdue lacked any evidence that OxyContin had a lower abuse potential.

If that's true -- if he testified to that -- assume he testified to that -- would you agree with that statement or disagree?

A. If you could just repeat the statement

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so that I can concentrate on it.

Q. That he testified Purdue lacked any evidence that OxyContin had a lower abuse potential.

MR. STRAUBER: Yeah, I object to the question. It's a very odd hypothetical question.

A. I don't know of any study that was done, but I don't know that no study was done. I just can't -- I can't tell you for sure.

You're referring to Purdue Frederick and you're referring to the time frame up to 2007 or 2010?

Q. Yes.

A. Okay. I just wanted to -- I don't know. My answer is the same, but I just wanted to be clear that my answer conformed.

Q. Has Purdue Pharma done a study since then?

A. We've done studies on abusability of many formulations, and we did them in the course of trying to develop and then select amongst several formulations. These were studies that were pioneered by Purdue with outside investigators, and they attempted to and, I think, quite -- would be considered today state-of-the art, to discern how easily practiced drug abusers might be able to defeat

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the delivery system and abuse it.
Q. Have you ever seen the deposition of Curtis Wright in the Poston case?
A. In the?
Q. Poston. P-O-S-T-O-N.
A. No, I have not.
Q. Did you ever discuss with Curtis Wright whether studies could have been done on the abuse potential of OxyContin prior to the release of OxyContin?
A. No.
Q. If he testified those studies were possible and could have been performed prior to the release of OxyContin, would it surprise you?
A. I would have to know more before I'd registered surprise or not. I'd have to know what he meant, what kind of studies and -- and so on. Perhaps he said we could have attempted to do it. That would surprise me less than if he said absolutely it could have been done. So I just have to know what he's talking about.
Q. This -- let me hand you this e-mail. Sorry about the delay there.
(Passing document.)
This is an e-mail from -- appears to

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be Richard Sackler on 8-27-97 to Craig A. McManama in Utah. That's a doctor; is that right?
A. The name is not familiar.
Q. If you will go to the -- why don't we mark this 36.
(DEPOSITION EXHIBIT NO. 36 MARKED)
Q. If you'll go to the bottom of the second paragraph, you write to him, "I am drawing your attention to our newest product, OxyContin Tablets (controlled-release Oxycodone HCI) and have included some literature. Most important to your practice, time of onset of OxyContin is as rapid as Immediate-Release Oxycodone, but duration is a full 12 hours and the patient reaches full blood levels in just two doses (one day)."
Was it your belief that the time of onset of OxyContin was as rapid as Immediate-Release Oxycodone?
A. That is what our data showed more or less. Almost as immediate. I believe in the study that I was referencing, but didn't reference in the note, I think it was 41 minutes for immediate-release and 45 minutes or something like that for OxyContin.
Now I recognize who he is.
Q. And who is he?

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A. He was a doctor who a friend in Utah was using. And he must -- it looks like he may have asked through his friend for me to send him some Betadine. He was a DPM, Doctor of Podiatric Medicine, and they do a lot of surgery, and Betadine is a necessary part of any surgical procedure. At least it's an antiseptic, and antiseptics are a necessary part.
Q. Let me give you a copy of this. And this is -- if we can mark this as Exhibit 37.
(DEPOSITION EXHIBIT NO. 37 MARKED)
(Passing document.)
Q. This is an e-mail dated May 15th, 1996. It looks like it was received by P. Goldenheim, M.D.
He does work at Purdue Pharma, correct?
A. Yes. He was --
Q. And it looks like you were also included by fax, Dr. Richard Sackler?
A. That's what it says.
Q. And if you go to the third page, it says, "Professor Dayer did not see any major problems regarding registration of OxyContin in Switzerland. Some specific points need to be clarified (monitored

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release approval as for DHC may be a possibility). He considers the following subjects as important and would need further investigations:"
The first paragraph says, "Information about the abuse/addiction potential versus other opioids because of the rapid onset of action of OxyContin."
Did I read that correctly?
A. You did.
Q. Did -- do you know if you obtained approval to sell OxyContin in Switzerland?
A. I believe we did.
Q. And did you provide him with the information about the abuse/addiction potential versus other opioids because of the rapid onset of action of OxyContin that he requested?
A. I'm not clear that he was actually requesting it, just saying that it was his opinion it was necessary for registration, but I don't know whether anything was produced. I doubt anything was produced here that was not produced for the FDA or the other European agencies who approved OxyContin. If anything was produced that was different, that is, additional studies, they would have also gone to the FDA.

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Q. Do you know why he was concerned about the rapid onset of action of OxyContin with respect to abuse and addiction?

A. I don't know.

Q. With respect to the claims about peaks and valleys, did you ever review the information to see what peaks and valleys were present in the plasma blood levels with respect to OxyContin?

A. In the five months did you say?

Q. No. Did you ever review --

A. I'm sorry. My hearing is not perfect.

Q. That's okay.

I said, with respect to peaks and valleys, the claim that peaks and valleys are different, did you ever review the literature regarding that?

A. I was familiar with some studies that demonstrated that. It was, to some extent, an obvious characteristic. Since the drug was taken twice a day, you'd have two peaks; whereas, the immediate release was taken four to six times a day and so you'd have four to six peaks.

Q. Do you know if the level of peaks and troughs are similar or different?

A. My recollection is that they are about

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the same. But that's a fuzzy recollection and I would need to see the data to refresh myself and be sure. I think you -- my recollection is they were close.

Q. Do you know whether the controlled-release, because it maintained a higher level and didn't have as much trough during the day, would be more likely to cause addiction or less likely to cause addiction?

A. I -- my impression is that the average blood level was the same, and I'm not certain -- so your question is, given that the average blood level is the same -- if I'm correct. And that's a recollection. I haven't seen that data for a very long time. The only difference -- the difference in the blood level, the remarkable difference, would be half as many or a third as many peaks and valleys.

And to the extent that somebody was seeking the drug or enjoying that element of the drug, the peak effect, I would think that the drug would be less attractive. But it's a conjecture, it's not knowledge, because I don't think we ever did a study that I'm aware of.

Q. My question is, if somebody has a controlled-release and maintains a higher level during the day with respect to valleys, they don't have as

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many valleys, does that cause -- is that more likely to make them become addicted or less likely, do you know?

A. I don't think the -- the valleys were about the same, too. So I don't think that the valleys or the height of the peak would have been any different. The principal difference, I think, would have been -- and you're saying "addictive" -- would have been fewer peaks. And all of this presumes that they were abusing the drugs as they were made and presented.

Q. And if they use it as made and presented, they would also be taking drugs for breakthrough pain potentially, correct?

A. They might well be -- have gotten two prescriptions from a physician.

Q. Right. If they -- you know, the studies show that it lasts from 8 to 12 hours, and if it lasts 8 or 9 hours in a patient and doesn't last until 12, he may need an additional prescription -- rescue prescription for that also, correct?

A. Possibly. I would have told the physician, use the rescue, compute the daily dose and try giving that dose as OxyContin twice a day; that is, half of that dose twice a day.

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Q. Do you know, was there any study done to determine whether patients who were given Controlled-Release OxyContin and then had to take another one, because it didn't last 12 hours, were more likely to develop addiction or less likely to develop addiction?

A. I know of no such study, and I don't recollect that anybody ever suggested such a study or such a hypothesis. I would have had -- I would have asked them why do you think that they are more prone or less prone to addiction. I wouldn't think it would make a difference. Again, not based on a study but based on a conjecture. So I really would have to understand what is the reasoning why -- why taking the drug three times a day would be more likely to cause addiction or less likely.

MR. THOMPSON: Could we go off the record one second?

VIDEOGRAPHER: We are off the record at 6:20 p.m.

(RECESS)

VIDEOGRAPHER: We are back on the record at 6:33 p.m.

BY MR. THOMPSON:

Q. What I'd like to do is have you sift

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through these documents, and with the exception of the GAO report, are all of these documents that are kept in the ordinary course of business at Purdue?

A. No, they would not all have been kept, to my knowledge, in the ordinary course of business. We would have had some sort of destruction policy. But we have been engaged in litigation for so long and so many different matters that basically, at least my documents I have, I don't think anything has been thrown away.

Q. Are these all documents that are generated in the ordinary course of business at Purdue?

A. Or at -- at Purdue Frederick or in other companies or some of the overseas companies, yes.

Q. Sure. Purdue Pharma and Mundipharma?

A. Purdue Pharma, Mundipharma, Purdue Frederick, whatever.

Q. And are all of these business records?

A. I don't know. You know, I'm not a lawyer.

MR. STRAUBER: I think that's asking for a legal conclusion.

MR. THOMPSON: I'm not sure it is.

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Q. Can you answer the question?

A. Okay. Are they business records? I really don't understand what that term means. It's not a term I've ever used, so -- they are what they are.

Q. I asked you about the OxyContin 20 milligram prescription. To your knowledge, was anything done to determine how many people put on 40 milligram, 80 milligram or 160 milligram prescriptions would become addicted or dependent if they took it for a certain period of time?

A. No.

Q. Sitting here today, after all you've come to learn as a witness, do you believe Purdue's conduct in marketing and promoting OxyContin in Kentucky caused any of the prescription drug addiction problems now plaguing the Commonwealth?

A. I don't believe so.

Q. Sitting here today, after all you've come to learn as a witness, do you believe that Purdue's conduct in Kentucky has led to an excessive or unnecessary amount of opioids being located throughout the Commonwealth of Kentucky?

A. I don't believe so.

Q. Do you believe that any of Purdue's conduct has led to an increase in people being addicted in the Commonwealth of Kentucky?

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A. No.

Q. Do you agree that education information presented by a drug company to physicians needs to be fair and balanced?

A. Yes.

Q. And do you agree if a company learns a physician does not understand a drug that is being sold by the company that they have a responsibility to educate them properly about the drug?

A. Yes.

Q. Do you think Purdue has an obligation to provide physicians with truthful information?

A. Yes.

Q. Do you believe Purdue provided any of the physicians in Kentucky with information that was not truthful?

A. No, I don't believe that.

Q. And is that because you don't believe any of the sales reps engaged in the conduct that is -- any of the sales reps in Kentucky engaged in the conduct that is described in the felony plea agreement?

A. That's my belief. I don't have any

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facts to inform me otherwise.

Q. And you never checked, did you?

A. I don't know how I would have checked that.

Q. Could you have looked at the call notes from your salespeople in Kentucky to see what they were telling physicians and whether it was the same information referenced in the felony plea agreement?

A. I could have looked at the call notes, but I believe that all the call notes were reviewed at least once and probably multiple times by many people.

Q. And why do you have that belief?

A. Because I know of the number of investigations and the extensive training and retraining that was done, and I believe it would have surfaced, any evidence of wrongdoing and been actionable.

But as I've said, I've only seen a few call notes, and the ones I've seen are so cryptic and imprecise and unclear in their references. Often you don't even know who's saying what. These were memory joggers that I've seen. They were written by a person who had a conversation who wanted to recall that conversation two, four, six weeks later.

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Q. And when the call notes say "I told the doctor about less abuse" or "I told the doctor the drug had less euphoria" or emphasized that, that would be improper, correct?

A. If such call notes existed and they were that explicit, yes. I didn't see any like that.

Q. Did it ever occur to you to check and see whether the people you hired and paid 50 million dollars for to do a presentation and defend Purdue in the U.S. Attorney's Office in the Western District of Virginia gave accurate and truthful information to the U.S. attorneys regarding the call notes?

MR. STRAUBER: I object to the form of the question.

You can answer.

A. It wouldn't occur to me that any attorney that we hired would give false information to any other attorney, and much less so to the U.S. attorney and his deputies.

Q. When doing a call note search, did you ever find out how they went about it?

A. I'm sorry?

Q. When -- when the people you hired did their call note search, did you ever find out how they went about it?

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A. At the time it was described fairly explicitly, but that was years and years ago. That was almost 15 years ago.

MR. STRAUBER: I think any further questions along this line will really impinge on attorney-client privilege, so I object.

Q. Was a breakdown of the results ever provided to you?

A. In a way, yes.

Q. When you say "in a way," how was it provided?

A. Well, I was told that --

MR. STRAUBER: Let me interrupt. I think your questions are really leading the witness into attorney-client communications, and I would direct him not to -- not to respond to those questions.

MR. THOMPSON: Well, certify the question and we'll talk to the judge about it. I think I'm entitled to go into it. If the judge says no, then of course we can't.

MR. STRAUBER: That's fine.

(Whereupon, the pending question was certified to the Court for ruling.)

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Q. So here's a call on a Marc Dubick in Lexington, Kentucky from a K. Boyles.

Do you know who that is?

A. I don't know either of those people.

Q. Under "Notes Memo" it says, "Got to convince him to counsel patients that they won't get buzzed as they will with short-acting."

Now, would that be an appropriate thing to do, counsel the doctor that the patients -- tell the doctor -- convince the doctor to counsel patients that they won't get buzzed as they will with short-acting?

MR. STRAUBER: Again, if you're reading from a document, please show the witness.

(Passing document.)

MR. STRAUBER: May I have a copy?

MR. THOMPSON: This is the only copy we have. You'll have to look at it together.

A. This is pretty easy to read. So could you repeat the question?

Q. Yes. Would it be appropriate to counsel the doctor -- to convince the doctor to counsel his patients that they would get less buzz with OxyContin versus --

A. Well, what it says here is that they

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won't get a buzz. And I don't think that telling a patient "I don't think you'll get a buzz" is harmful, because if they do, I would think that the patient would report it and he would know, oh -- I don't know why he would have told this to a patient. But I think that it actually could be helpful, because many patients won't get a buzz, and if he would like to know if they do, he might have had a good medical reason for wanting to know that.

Q. Do you know whether telling patients they won't -- telling doctors patients won't get a buzz was one of the things prohibited by the -- in the statement -- Agreed Statement of Facts in the felony plea?

A. Yes. But that isn't what it says. He said -- we don't know what the conversation was between the doctor and the rep. But, as I've testified just a minute ago, I could see that this could have been not only -- not harmless, but helpful.

Q. Here's one --

MR. STRAUBER: Are you going to mark that as an exhibit?

MR. THOMPSON: No, I'm just going to ask him about these.

Q. Here is one --

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MR. STRAUBER: The only difficulty I have with that is, you're asking him questions about them and then we, going forward from here, have no record of what it is he was looking at.

MR. THOMPSON: Well, this is my only copy. That's why I don't want to --

THE WITNESS: You can keep it.

MR. STRAUBER: Why don't you mark it as an exhibit, don't give me a copy --

MR. THOMPSON: If you want to mark it later, you can, but I'm going to ask him my questions right now so I can get out of here.

MR. STRAUBER: I object to this line of questions.

MR. THOMPSON: You can object. I don't have to mark it if I don't want.

Q. Here is Ellen Ballard in Louisville, Kentucky, sales rep Mark Curran.

Do you know who that is?

A. Yes.

Q. And in here it says, "Talked of less euphoria and more convoluta with Oxy."

Would it be inappropriate to tell patients they get less euphoria with Oxy?

A. We really don't know what was said.

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As I said, this is a memory jogger. He might have said, "There may be less euphoria," or, "Some people have less euphoria," or -- we just don't know what was said here.

Q. Okay.

A. If all he said was "There may be less euphoria," that could be true, and I don't see the harm. If he promised less euphoria, it shouldn't have been said.

Q. An Agreed Statement of Facts doesn't say you have to promise less euphoria, it says if you mention to a doctor or infer that it causes less euphoria, that's improper, correct?

A. That was what we agreed to, yes. But this was 1998, long before there was an Agreed Statement of Facts.

Q. What difference does that make? If it's improper in 2007, wouldn't it be improper in 1998?

A. Not necessarily.

Q. Well, the improper conduct that the Agreed Statement of Facts -- the time period was 1996 to 2001, correct?

A. Yes.

Q. And if this is 1998, it's within that

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time period, correct?

A. Yes.

Q. So by what kind of twisted logic are you saying that saying this in 1998 wouldn't be improper because the -- because the Agreed Statement of Facts is in 2007?

MR. STRAUBER: I object to the form of the question. It isn't a question; it's argumentative, and it's really uncalled for.

Q. If you can answer, go ahead.

A. I think I should stand on what I said.

Q. Well, let me ask you this. Tell me all the bases you have for believing that saying this in 1998, to talk of less euphoria with Oxy, would somehow not be a problem because the agreed statement was in 2007?

A. I don't know what he said in 1998. I know what he wrote, but I don't have quotes on it, I don't have a dialogue. I wasn't present. I don't know what he said. And I don't even know whether this was a document upon which the Agreed Statement of Facts was constructed. For all I know, this document was tossed away as inexact or inexplicit.

Q. Let me ask you about this document.

James Donley is the doctor at the Trover Clinic in

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Madisonville, Kentucky who was called on by Holly Will. The note's memo says, "Quick, reminded him that Oxy gives flat blood levels, so less buzz than Lortab."

Is that the type of statement that's prohibited by the Agreed Statement of Facts?

A. I don't know that that's what she said. If you're asking me a hypothetical, I would say that this is not -- neither accurate nor appropriate. It doesn't actually give flat blood levels as you know, and as our rep knew and as any doctor who had been properly presented the product would know. But, nevertheless, even though it is demonstrably wrong, it would be still inappropriate to say on two bases; on the basis of the Agreed Statement of Facts and also on the basis it's untrue.

But, again, I have to emphasize, these are not transcripts. These are about as distant from transcripts as anybody can get. This is a memory jogger, and I don't know what she said, and I find it hard to believe that she said anything like this. This was to remind her of a discussion.

Q. Have you ever spoken to her?

A. No.

Q. Okay. This is Dr. David Parks in

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Bowling Green, Kentucky, who was called on by Philip Gross. "Love the idea of getting effective pain relief, but not euphoria to get rid of druggies."

(Passing document.)

If it was discussed with him that it gives effective pain relief but not euphoria and he loved the idea, would that be inappropriate comments to make?

A. Yes. If our rep made it. If the doctor made it, I don't think that it's -- it may be erroneous, but it isn't improper. And I don't know who made the statement.

Q. If the rep made it --

A. Or, in fact, even what statement was made. I have not -- I don't remember seeing any of these notes, by the way. But these are typical. They are fragments of fragments of fragments of a conversation that are designed to remind the rep of a conversation that he or she had two, three, four, five, six weeks prior. So they mean a lot, but without asking the person who wrote them what it meant, we don't, sitting here, have any idea what it means.

Q. If the -- if the Purdue sales rep calls on a doctor in Kentucky and explains to him that

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Oxy has less potential for abuse due to its sustained release, would that be improper and the type of statement that was agreed was improper in the Agreed Statement of Facts when Purdue pled guilty to a felony?

A. Okay. State the hypo --

THE WITNESS: Could he just restate the hypothetical question?

Q. Sure. If Purdue called -- I want you to assume a hypothetical. If Purdue called on a doctor and said that OxyContin has less potential for abuse due to its sustained release, would that be the type of statement that would be inappropriate?

A. And when was that said? You're going to set a time limit to it or a time period to that hypothetical?

Q. No. I'm just trying to get an idea of what statements you consider inappropriate versus appropriate.

Would that be an inappropriate statement for a rep to tell a doctor?

A. Today, yes.

Q. Would it have been inappropriate from 1996 to 2001?

A. I'm not sure, because I'd have to look

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at the package insert and could see was that in the package insert or was it reasonably the same as what was in the package insert. I'd have to do a textual analysis. It's close to what was in the package insert, very close, but it might have drifted away from the package insert so that at that time it was inappropriate. But I'm not sure because I have to read the two -- the hypothetical statement you put forward and the package insert to give you an opinion as to whether it has drifted away from the package insert.

Q. It would be pretty easy to tell if we looked at the Agreed Statement of Facts because they outlined the comments they felt were improper between 1996 and 2001, correct?

A. I didn't memorize the Agreed Statement of Facts either. But, yes, if that statement was an example of an inappropriate statement, obviously it would -- we agreed it was inappropriate.

Q. And these call notes, you-all actually required your -- your representatives or salespeople to do call notes and instructed them to do them within minutes of completion of the call, correct?

A. That's correct.

Q. And that's because the information

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recorded is generally more accurate when it's recorded immediately after the sales call while the events of the call are fresh in the representatives' minds, correct?

A. I don't think that that would be true in the way these call notes were used -- written or used when reviewed. I don't think it would have mattered if they had done it that evening.

But when the system was -- or when that policy was established, whoever established it probably had a different use in mind and expected them to be much, much more -- much closer to a "he said, I said," "he said, I said," "he's interested in this, I have to get him an answer for that."

And the notes I've seen so far depart so far from that that I don't think it mattered whether they did it in a minute, an hour or a day. So long as the conversation was fresh in their mind, they sketched some notes to remind them of the conversation a few weeks later, two to six weeks later.

Q. When you disciplined people, how did you make a determination which ones needed to be disciplined -- sales reps needed to be disciplined?

A. I didn't discipline anybody and so I was not asked to make a determination.

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Q. Do you know if the people who did make that determination relied on the call notes in determining whether discipline should take place?

A. I don't know.

Q. Do you know if the reps in Kentucky were disciplined for having inappropriate call notes that reflected their conversations with physicians?

A. I don't know.

Q. If a sales rep went to a doctor and said "Discussed lack of buzz and, thus, won't be drug seeking," would that be an inappropriate comment to make?

A. Could you form the comment for me, since it's a hypothetical, as a sentence and then I'll respond to it?

Q. If a sales rep went to a physician and said, "You don't get a buzz with OxyContin," would that be an inappropriate comment?

A. Yes.

Q. If a sales rep went to a physician --

MR. STRAUBER: I have to -- you're going through a whole line of questioning where you have documents, you purport to be reading from them, you're not showing them to me, you're not showing them to the witness. I don't think it's a fair line of

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inquiry.

MR. THOMPSON: I'm asking him what types of questions a sales rep says. Whether I've got notes or documents or I've got them in my head doesn't matter. I get to ask my questions. You can follow up if you want.

MR. STRAUBER: You appear to have documents in front of you that you're reading from.

Q. If a salesman went in and discussed abuse potential and benefits of Oxycodone -- OxyContin -- I'm sorry -- and it not giving a euphoria, would that be inappropriate?

MR. STRAUBER: Objection.

A. I believe that would be inappropriate.

Q. If he tells them that there's less euphoria with OxyContin, he or she, the sales rep, says there's less euphoria with OxyContin, would that be inappropriate?

A. Less amount of euphoria or less likely to be euphoria or something else?

Q. Either of those.

A. I believe that today that would definitely be inappropriate.

Q. Would it have been inappropriate between 1996 and 2006?

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A. I would have to study the package insert.

Q. Let me -- let me go back and talk about what -- maybe this will help us here.

Under "Misbranding of OxyContin" there were several things that were brought up that were -- were inappropriate. And it says, "With the intent to defraud or mislead" --

MR. STRAUBER: Are you reading from the Agreed Statement of Facts?

MR. THOMPSON: I'm reading from page 5 of the Agreed Statement of Facts.

A. What number is that?

MR. STRAUBER: It's Exhibit 33.

A. I'll have to find it now. Is this it?

Q. Yes.

A. And where are you reading from, please?

Q. Page 5, paragraph 20. "With the intent to defraud or mislead" -- I'm sorry. Let's back up.

"Purdue's supervisors and employees, between December 12th, 1995" --

MR. STRAUBER: Again, you left out the word "certain."

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MR. THOMPSON: Sorry. Well, I'll just read it in its entirety, then.

MR. STRAUBER: Okay.

Q. "Beginning on or about December 12th, 1995 and continuing on or about June 30th, 2001, certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, less likely to cause tolerance and withdrawal than other pain medications."

Did I read that correctly?

A. I think so. It's getting late, so I might have missed, too.

Q. And it was a review of the call notes by the U.S. Attorney's Office that formed the basis of this plea agreement, correct?

A. I don't know that.

Q. Did you ever review any of the documents filed by the U.S. Attorney's Office in the case where Purdue pled guilty to the felony?

A. No, I didn't.

Q. All right. And it says here --

A. They didn't footnote these documents, so I don't even know if they -- the documents -- they reviewed millions of documents. I don't know whether

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they referenced any of the documents to this. I certainly couldn't have reviewed millions of documents. No one person could have done that.

Q. Under number -- subparagraph "e" it says, "Told certain healthcare providers that OxyContin did not cause a 'buzz' or euphoria."

And that would be improper, correct?

A. It depends on -- oh, did not cause. Yes, that would be inappropriate.

Q. "Caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to 'weed out' addicts and drug seekers."

A. In its totality, it's inappropriate.

Q. And one of the things that it points out in here, when we went on, was the osteoarthritis study.

Do you remember us talking about that?

A. I do.

Q. Here's Carol Neilheisel, sales rep. This is William Yates, doctor, Florence, Kentucky. And the note's memo says, "Brought osteoarthritis studies that show non-addiction. Discussed how he could use Oxy to deter addictive behavior. Less

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pills, less potential for abuse."

(Passing document.)

Would you agree that those comments would be improper and inappropriate?

A. If they were quotes of the transcript or of what he said, yes, this is inappropriate.

Q. And --

A. In its totality it's inappropriate.

MR. STRAUBER: Are you planning to mark this as an exhibit?

MR. THOMPSON: I was not going to mark it, no.

Q. And it says here, "Purdue states that" -- I'm reading from the reply of the United States to Defendant's response to Blue Cross/Blue Shield of Tennessee, another private third-party's request for restitution.

(Passing document.)

A. This is a new document, right?

Q. Uh-huh.

A. Is this an exhibit or not?

Q. I just want to ask you about some of the information in here.

MR. STRAUBER: You're not going to mark this as an exhibit either?

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MR. THOMPSON: I wasn't going to.

MR. STRAUBER: Could you identify it so we'll know what it is?

MR. THOMPSON: I thought I did. It's the reply of the United States to Defendant's response to Blue Cross/Blue Shield.

Q. I'm looking at the third paragraph. "Purdue states an analysis of the notes that Purdue's sales representatives kept from their visits to physicians revealed that less than .2 percent contained any evidence of statements that were arguably improper."

Were you aware that they had claimed that two-tenths of one percent of the sales notes were arguably improper?

A. As they say, actually, here in their response, "were even arguably improper."

Q. But the U.S. attorney says, "This bare statistical reference does not provide a complete picture of the magnitude of the unlawful activity described in the information in the Agreed Statement of Facts. In fact, these very same notes show the pervasive nature of the false and misleading statements.

"For example, according to the notes,

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in at least 41 states physicians were informed that addicts would not like OxyContin or that OxyContin could be used to weed out drug seekers because addicts would not like it. In at least 49 states physicians were informed that OxyContin produces no 'buzz' or euphoria, and in 50 states physicians were informed that OxyContin had less abuse potential than other opioids."

Would all of those comments be improper?

A. Those comments would be improper, yes.

Q. This says, "In addition, once Purdue learned of the investigation, it conducted training that cautioned sales representatives to avoid including references to the false and misleading statements in their call notes. Eventually Purdue changed the call notes system altogether to preclude such references by allowing sales representatives to choose only from preselected menu items that, not surprisingly, omitted the false and misleading statements that the employees had previously -- that the employees previously -- had previously spontaneously recorded in the notes."

Were you aware of that?

MR. STRAUBER: I object to the form of

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that question. You're showing the witness an argument written by the government and submitted to the Court in a brief that this witness has never seen. There are government arguments and you're asking if he was aware of it.

MR. THOMPSON: I'm asking if he was aware of that activity.

A. What activity?

Q. That "Once Purdue learned of the investigation, it conducted training that cautioned sales representatives to avoid including references to the false and misleading statements in their call notes." That's number one.

Were you aware they did that?

A. I don't think they did that.

Q. And it says, "Eventually Purdue changed the call notes system altogether to preclude such references by allowing sales representatives to choose from preselected menu items that, not surprisingly, omitted the false and misleading statements that the employees had previously spontaneously recorded in their notes."

Were you aware that that had occurred?

MR. STRAUBER: Well, I object. You're assuming that something occurred based upon an

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argument of one party to a litigation in a brief.

MR. THOMPSON: All right.

A. Can I verify that this occurred? I can't.

Q. The statements referenced in the Agreed Statement of Facts under "Misbranding of OxyContin" --

A. I don't even see a date on this.

Q. The statements --

A. I'm sorry. Can we -- are we on the same document, or not?

Q. No. I'm asking about the Agreed Statement of Facts now.

A. Oh, okay, we're back on that. Okay.

Q. The statement under "Misbranding of OxyContin" --

A. What page or what number?

Q. Page 5. You've read paragraph 20 in its entirety, correct?

A. I had read it, but it might help me to read it again. But why don't you pose your question?

Q. Are those the statements that were improper and constituted the guilty plea?

A. Of Purdue Frederick?

Q. Yes.

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MR. STRAUBER: Can I hear the question again? I just missed it.

Q. The statements outlined in paragraph 20, are those the improper and misleading statements that were made with intent to defraud by Purdue's sales force? Does that set them forth?

A. I don't know. To me this is almost a legal question, and I'd like to know whether our attorneys would agree with this or not. These are some of the statements that are in here. I think there are others. So I'm not sure that you mean is this all and nothing else.

Q. I don't mean -- I just mean under paragraph 20 --

A. Okay.

Q. -- would that constitute --

A. Examples of?

Q. -- examples of inappropriate and --

A. That's what --

Q. -- misleading statements?

MR. STRAUBER: I object to the question. It's been a long exam, we're late in the day, and now you seem to be going over the Agreed Statement of Facts again and asking the witness what the Agreed Statement of Facts says. What it says is

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written in the Agreed Statement of Facts.

MR. THOMPSON: Yes.

MR. STRAUBER: I don't know where this is getting us. At this late hour I think it's starting to border on harassment.

MR. THOMPSON: Can you read my question back?

(Record read.)

THE WITNESS: Should I answer?

MR. STRAUBER: I object, but you can answer, yes.

A. Yes.

Q. If a sales rep told a doctor that using OxyContin would provide smoother blood levels, would that be an appropriate statement?

A. I don't know -- if smoother blood levels was not in the package insert, it may not -- it might be an inappropriate statement, but I'm not sure that it wasn't in the -- in the package insert. Although it might be inappropriate, I don't know.

It would have been true depending upon what was meant by "smoother." "Smoother" is not a medical term or a pharmacokinetic term. It's an opinion of -- it's a term that somebody might apply to a graph. It's a smoother line; it's not a smoother

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line. But it's not really a clear statement and, thus, I can't say it's clearly right or clearly wrong. It would have been fine if that terminology was in the package insert. I don't know whether it was.

Q. All right. What information did you review to prepare for your deposition today?

A. Documents.

Q. Which documents?

A. Not too many of the ones you've shown me. This Agreed Statement of Facts we reviewed in part.

Am I supposed to answer this? I mean, I don't --

Q. Yes. Any other documents that you reviewed?

A. That I recall and can describe to you?

Q. Yes.

A. No.

Q. You did say you reviewed six -- less than eight call notes; is that right?

A. Yes.

Q. And that was the first time you'd seen call notes?

A. Yes. This was the second time. And as I said, they are both -- both experiences are the

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same. They are so fragmentary that they can mean -- it's impossible to know really what was said. That's why you had to pose hypothetical statements.

Q. Yes. Purdue Pharma, L.P., Purdue Pharma, Inc., The Purdue Frederick Company, Purdue Pharmaceuticals, L.P., P.F. Laboratories, Inc., do you know if they have the same directors or are there different directors for those entities?

A. I don't know.

Q. Do you currently practice medicine?

A. No. Not practice in the sense that I have an office or see patients by appointment, no, I don't.

Q. When is the last time that you practiced medicine?

A. In 1974 during my residency.

Q. From 1999 to 2002 you were the president of Purdue Pharma, L.P.?

A. From the very last days of '99 until March of 2003.

Q. Were you also at some point the president of Purdue Frederick?

A. I don't think so, no.

Q. Did you have any office title at Purdue Frederick?

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A. I did.

Q. What was that title?

A. I was a senior vice president.

Q. And do you know when you relinquished that title?

A. I don't recall, but it probably was either simultaneous with ending my presidency at Purdue Pharma or before.

Q. There are different types of corporations. There are not-for-profit corporations and there are for-profit corporations.

Would I be correct that Purdue Frederick and Purdue Pharma are for-profit corporations?

A. They're for-profit businesses, but not all of the companies that you've named are corporations.

Q. All right. That's a good distinction.

Would I be correct that Purdue Frederick or Purdue Pharma are for-profit not not-for-profit?

A. They're for-profit.

MR. THOMPSON: Can we go off the record a minute?

VIDEOGRAPHER: We are off the record

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at 7:18 p.m.

(RECESS)

VIDEOGRAPHER: We are back on the record at 7:39 p.m.

BY MR. THOMPSON:

Q. All right. Let's go back through -- I'm going to hand you a document that is at the top -- let's mark this as Exhibit 38.

(DEPOSITION EXHIBIT NO. 38 MARKED)

Q. It's from Richard Sackler. Do you recognize that?

A. I recognize the name. Okay.

Q. All right. Was this an e-mail that you sent to Michael Friedman?

A. Yep.

Q. And it says here under "importance" down below, "Importance: Low." But down below it says, "Why don't you guys plan a presentation about addiction that could be given first by RR or BK..."

Now, who are those individuals?

A. Robert Reder or Bob Kaiko.

Q. "...and eventually by our senior managed healthcare people."

Next paragraph, "I think that Paul has a good point, but we should consider that 'addiction'

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may be a convenient way to 'just say no,' and when this objection is obliterated, they will fall back on the question of cost. Unless we can give a convincing presentation that CR products" -- that's controlled-release products, is that what that is?

A. Yes.

Q. -- "are less prone to addiction potential, abuse or diversion than IR products" -- is that immediate release?

A. Yes.

Q. -- "I think that this can be done, but I defer to BK and RR and other experts."

A. Yes.

Q. What were you trying to accomplish there by trying to show that controlled-release products are less prone to addiction, abuse or diversion than immediate-release products?

A. Well, I wasn't trying to show anything. I was basically asking the question. And if the answer were yes, we can put together a good, effective and medically correct presentation, I thought it would be useful to do so. But I was asking them can we do that, do we have the information, do we have the data, and obviously if we had contrary information or data, then obviously I couldn't do

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that.

Q. Are you aware of any presentation showing that controlled-release products are less prone to addiction, potential abuse and diversion than immediate-release products was ever done?

A. No, I don't think so, but I don't remember how this came to an end. I put on low in importance to indicate it was not something that was urgent, it was an idea I had, and I said, Can we do this.

Q. Then another e-mail I'm going to hand you, we'll mark this as Exhibit 39.

(DEPOSITION EXHIBIT NO. 39 MARKED)

(Passing document.)

Q. And this is dated -- it looks like at the bottom "Analgesic Plans, Dr. Richard Sackler at Norwalk."

And is this an e-mail that you sent?

A. Yes. It's quite a dense e-mail.

Q. And if you go back to page 3, the e-mail that preceded it was from John Stewart.

A. Yes.

Q. Who is John Stewart?

A. He was the general manager in Canada, PF Canada.

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Q. And is that a Purdue Pharma affiliate?

A. It's an affiliated company, yes.

Q. Does the Sackler family own PF Canada?

A. Yes. Yes, we do.

Q. He says under the first paragraph, "In my opinion, the action that will produce the greatest sales gains are the acquisition of IMS's practice quartile data and the resulting improvement in targeting of our sales and marketing activities."

What does that mean?

A. In the United States from the inception of the launch of OxyContin, we focused our salesmen's attention to physicians who were, based on their history, physicians whose practice and their practice was to use -- write a lot of prescriptions for opioids. We didn't go to people who didn't write them, we went to people who did.

And I don't recall whether this practice was or was not done in PF, but I might have learned in a meeting that they were not doing it and they could not purchase the same data source from IMS in Canada, but they appear to have had something that would have been similar where they divided physicians into quartiles.

Q. And if you look at your response to

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him on 9-27-96, you say, "Your most important question to me was: Have physicians been reluctant to use Oxy p.r.n." --

What does Oxy p.r.n. mean?

A. I assume that Oxy referred to OxyContin. P.r.n. would mean as needed.

Q. -- "in place of IR forms of Oxycodone."

And that's Immediate-Release Oxycodone, correct?

A. Right.

Q. "I've not asked this question, but judging from the very strong sales performance and continuing growth, I would guess that this has not been a problem. I think that were this the case, it would be because of the very rapid rate of onset (as fast as IR Oxycodone, that is, 45 minutes versus 41 minutes for the IR form - not even close to a significant clinical or statistical difference)."

And was it your understanding when you wrote this that OxyContin Controlled-Release did not have a significant clinical statistical difference with rate of onset when compared to Oxycodone Immediate-Release?

A. That's correct. This was drawn from a

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study that was done. "Onset" is not defined here, but it was a medical term in the trial that, I believe, John Stewart had either been given or was familiar with which basically recorded the first instance where the patient said, Oh, I'm beginning to feel better, my pain is less. That was meant by "onset." That was the meaning of "onset" in that trial. And that was what I was quoting from.

Q. And it says here, "The fast rise character (now a patent in the U.S.) of the drug combined with familiarity and a marketing program that emphasized that IR was the old was" -- I think that's supposed to be "way" --

A. Yes.

Q. -- "and OxyContin Tablets are the new way to treat moderate to severe pain has resulted in our success."

Did I read that correctly?

A. You read -- you read very correctly what is written here.

Q. When it says "the fast rise character," you're referring to OxyContin having a fast rise as far as when relief occurs, correct?

A. Yes.

Q. And then down below that, if you go to

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about the fourth paragraph, "The overall schema that Marketing here has worked our for three of the four" -- I think that's "out of three of the four" should probably be. But it's written, "The overall schema that Marketing here has worked our for three of the four is: Oxy - 1. IR old way, OxyContin Tablet, new way, emphasizing the b.i.d. was q. 4h." And that's --

A. Versus. Versus.

Q. "...b.i.d. versus q. 4h and underscoring the similarity of onset. Other differential benefits are emphasized, such as range of doses, the very small tablets, et cetera."

And then Oxy - 2, your second point with regard to Oxy, is, "In cancer and severe non-malignant pain, the one to start with and the one to stay with. Here we are going directly after the MSC and Duragesic business."

What is MSC?

A. MS Contin.

Q. And Duragesic, who made Duragesic?

A. J & J.

Q. And you say, "Clearly" -- this is highlighted -- or capitalized. "Clearly this strategy has outperformed our expectations, market research and

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fondest dreams."

A. Yes.

Q. Did I read that correctly?

A. You did.

Q. All right. And then the last one I want to ask you about --

A. There's no question?

Q. No.

When you say it outperformed your fondest dreams, you're talking in terms of market share and what it was earning; is that correct?

A. It's the overall sales trajectory.

Q. And then I've got one more e-mail to ask you about. Who was -- I'm sorry. Let's mark this as No. 40.

(DEPOSITION EXHIBIT NO. 40 MARKED)

Q. Did you read the sales bulletins when you were the -- when these were sent to you?

A. I was senior vice president. Not generally. I might have scanned this. I didn't read them carefully. They were very carefully crafted by sales and marketing people and others and I didn't usually read them.

Q. Who is Russ Gasdia?

A. Russ was then either a district

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manager or a regional manager.

Q. And this is January 25th, 1999. "Prescription Sales Force."

Does that mean it went out to everybody?

A. No. It probably means it went out to salesmen who were doing -- who were selling the prescription products.

Q. Well, would it have gone to everyone selling OxyContin?

A. I believe so, yes.

Q. And the first paragraph says, "...effective with the first quarter 1999, MS Contin sales volume and growth" --

A. First paragraph. I see "As was announced..." Okay?

Q. "As was announced at the national meeting..."

A. Right.

Q. I skipped that.

A. Okay. Right.

Q. "...effective with the first quarter 1999, MS Contin sales volume and growth as well as quota will be calculated at .50 cents for every $1.00."

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A. I'm not following you. Can you just show me where.

MR. STRAUBER: I have the same problem. I don't know where you're reading from.

Q. The first paragraph.

A. Okay. I'm looking for "effective." Oh, I see. Okay. Sorry. These are small and I can't read them that fast. I'm now following you.

Q. Let me give you this one and we'll make it the exhibit.

A. Okay. I'm following you now.

Q. Sure. So let's read the first paragraph. "As was announced at the national sales meeting, effective with the first quarter 1999, MS Contin sales volume and growth as well as quota will be calculated at .50 cents for every $1.00." What does that mean?

A. I -- I can't be sure, but I think that we were reducing the bonus for MS Contin. I'd have to read the whole thing to be sure of that. Would you like me to read it all?

Q. That's all right. I'm going to read it with you here.

A. Oh, okay.

Q. The next sentence says, "OxyContin sales volume and growth as well as quota will be calculated at $1.15 for every $1.00."

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A. Again, it was de-emphasizing MS Contin sales growth and increasing the incentive by a small amount on OxyContin sales growth.

Q. And then the next paragraph says, "Early estimates indicate that the fourth quarter 1998 bonus payout will be another record payout. Remember, this record payout came at a time when we were utilizing a factor of .55 cents for every MS Contin dollar and $1.15 for every OxyContin dollar. As we continue to drive more business toward OxyContin, each of you will benefit significantly from the factoring of $1.15 for every $1.00 of OxyContin." Again, is that referring to de-incentivizing MS Contin sales and incentivizing OxyContin sales?

A. Yes. We were moving the incentive program to focus on OxyContin. And every time you take an incentive program, reduce it, you have, at least in some of the people who are affected, some strong negative feelings, and that's probably why there was a small increase to OxyContin. It looks like it was 15 percent. But I'm interpolating here. I don't recall. I certainly didn't read this and I

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don't recall the details of the incentive compensation well enough to be sure.

Q. And then it says, "As pointed out, your priority is to sell, sell, sell" -- and that's in bold -- "OxyContin."

A. Right.

Q. And is that what the sales force was instructed to do?

A. That's what he said they were instructed to do. But they were instructed to do their best to sell OxyContin, I guess. This was a sales force related kind of rah-rah piece.

Q. And it also says, in the last paragraph, "Remain focused on positioning OxyContin as the opioid to start with and stay with in chronic, malignant and non-malignant pain states. In addition, continue to aggressively position OxyContin for use in osteoarthritis, low back pain, post-neuropathic neuralgia and post-surgical applications where appropriate. Finally, continue to highlight the advantages of OxyContin, especially for use in the elderly. If you have any questions regarding the bonus calculations for the first quarter of '99, please contact your district manager."

A. That tells me he was a regional manager then.

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Q. Have you made any effort, or as we sit here today do you know how many patients who took OxyContin in Kentucky became dependent or addicted?

A. No.

Q. Do you believe that an inappropriate number of patients or an excessive number of patients who took OxyContin in Kentucky became addicted or dependent?

A. No.

Q. Do you know or has Purdue made any effort to ascertain how many people who were started on OxyContin wound up becoming dependent and moving on to heroin at some point?

A. No.

MR. THOMPSON: I think that's all the questions I have, Dr. Sackler. Thank you very much.

THE WITNESS: Are we finished? Or maybe not. I don't know.

MR. STRAUBER: No questions.

VIDEOGRAPHER: That is the conclusion of this deposition. We are off the record at 7:58 p.m.

(Deposition concluded at 7:58 p.m.)

* * * * *

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STATE OF KENTUCKY)(
COUNTY OF JEFFERSON)(

I, LAUREN I. GOOTEE, Notary Public, State of Kentucky at Large, hereby certify that the foregoing deposition was taken at the time and place stated in the caption; that the appearances were as set forth in the caption; that prior to giving testimony the witness was first duly sworn by me; that said testimony was taken down by me in stenographic notes and thereafter reduced under my supervision to the foregoing typewritten pages and that said typewritten transcript is a true, accurate and complete record of my stenographic notes so taken.

I further certify that I am not related by blood or marriage to any of the parties hereto and that I have no interest in the outcome of captioned case.

My commission as Notary Public expires March 26, 2017.

Given under my hand this the _____ day of _____, 2015, at Louisville, Kentucky.

Lauren I. Gootee

LAUREN I. GOOTEE
NOTARY PUBLIC

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